DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND
2748 Worth Road
JBSA FORT SAM HOUSTON, TEXAS 78234-6021

Freedom of Information/
Privacy Act Office (20-00785)

22 February 2021

New England Anti-Vivisection Society
ATTN: Mr. Russ Kick
333 Washington Street
Boston, MA 02108

Dear Mr. Kick,

This letter is in response to your Freedom of Information Act (FOIA) request for the U.S. Army Research Institute of Environmental Medicine, U.S. Army Medical Research and Materiel Command, most recent Program Description, Animal Care and Use Program, for the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). I apologize for the delay in responding to your request which was caused by the need to consult with a number of agencies.

Enclosed is the document responsive to your request. Your request has been processed in accordance with the Freedom of Information Act (FOIA), 5 United States Code (U.S.C.) § 552 and the Privacy Act (PA) 5 U.S.C. § 552a. In accordance with the Freedom of Information Act, information has been withheld (redacted) based on the following exemptions:

Exemption (b)(2) permits the withholding of records related solely to internal rules and practices of an agency.

Exemption (b)(4) permits the withholding of records related to commercial or financial information in connection with bids, contracts and proposals or other proprietary data.

Exemption (b)(5) permits the withholding of information under the deliberative process privilege, including pre-decisional documents, draft documents, or information that could be withheld under civil discovery, attorney-client, or attorney-work product privileges. Deliberative information consists of recommendations or opinions on legal, policy, or other matters. Pre-decisional information includes inter-agency or intra-agency communications that are antecedent to the adoption of the agency decision. Exemption 5 protects against the premature disclosure of proposed policies and recommendations before they are finally adopted and protects against the public confusion that might result from the disclosure of reasons and rationales that may not ultimately be the grounds for an agency's action.

Exemption (b)(6) permits the withholding of personally identifying information of personnel currently or recently assigned within a particular component, unit,

organization, or office within the Department of Defense (DoD) in response to requests under the FOIA. Information withheld includes name, rank, e-mail address and other identifying information regarding DoD personnel and additionally includes the withholding of rosters, directories (including telephone directories), detailed organizational charts, line drawings of building locations, schematics, and room numbers in order to protect the component's or individual's privacy concerns. When weighing the public interest in knowing how the government works against the privacy interests and security concerns of DoD personnel, we may conclude that no significant public interest will be served in the release of that information. Exemption 6 provides reasonable assurances that personal privacy interests are protected and that the identity of any particular individual cannot be ascertained.

Because your request has been partially withheld (redacted), you are advised of your right to appeal this determination to the Secretary of the Army. If you decide to appeal at this time, your appeal must be submitted within 90 days of the date of this notification. In your appeal, you must state the basis for your disagreement with the partial denial and the justification for the release of information associated with your request for this command. Your appeal should be addressed to: CDR U.S. Army Medical Command, Attention: Freedom of Information/Privacy Acts Office (MCPA), 2748 Worth Road, JBSA, Fort Sam Houston, Texas 78234-6021, for forwarding, as appropriate, to the Office of the Secretary of the Army. Please enclose a copy of this response along with your Appeal.

For any further assistance and to discuss any aspect of your FOIA request, you have the right to contact the Army FOIA Public Liaison Officer, Ms. Alecia Bolling, by email at us.army.hqda-oaa-ahs.mbx.rmda-foia-public-liaison@mail.mil, or by phone at (703) 428-6238. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration (NARA) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: NARA-OGIS, 8601 Adelphi Road-OGIS, College Park, MD 20740-6001, email at ogis@nara.gov, telephone number (202) 741-5770 (toll free at (877) 684-6448), or by facsimile (202) 741-5769.

Should you have any questions pertaining to the processing of your request I may be reached at (210) 466-5933 or email john.p.peterson.civ@mail.mil

Respectfully,

John P. Peterson
Chief, Freedom of Information/
Privacy Acts Office
U.S. Army Medical Command

Program Description

Animal Care and Use Program

U.S. Army Research Institute of Environmental Medicine

United States Army Medical Research and Material Command (USAMRMC)

(b)(6)

Natick, MA 01760

01 February 2018

for

AAALAC International

Table of Contents

Appendices

Program Description

Section 1. Introduction

A. State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

The program unit is the United States Army Research Institute of Environmental Medicine (USARIEM) (b)(6) on the grounds of the Natick Soldier Systems Center, Natick, Massachusetts. USARIEM serves as the Department of Defense's lead biomedical research laboratory that conducts basic and applied research on environmental factors that affect the health and performance of military personnel. One additional facility belongs to the program unit, the Pike's Peak Altitude Research Laboratory, in which no animal research is conducted. USARIEM, commanded by (b)(6) (b)(6) is a laboratory of the United States Army Medical Research and Materiel Command (USAMRMC) commanded by (b)(6) and located at Fort Detrick, Maryland. The USARIEM Commander serves as the Chief Executive Officer and Institutional Official for the program unit.

B. Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

USARIEM is a Department of Defense (DoD) laboratory that conducts basic and applied research to determine how exposure to extreme heat, severe cold, high terrestrial altitude, occupational tasks, physical training, deployment operations and nutritional factors affect the health and performance of military personnel. The broad mission of the Institute is to protect, sustain and enhance the health and performance of individual military personnel and troop populations. USARIEM's animal use program supports studies that focus on elucidation of the pathophysiological mechanisms of environmental, combat-related, and/or exercise-induced injuries, illnesses, or decrements in both physical and mental performance. Studies evaluating the efficacy of innovative prophylaxes, therapies, and environmental interventions are primary areas of interest.

C. Note that AAALAC International's three primary standards are *the Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC, 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and

use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

1. The Guide for the Care and Use of Laboratory Animals (Guide), NRC, 2011
2. Animal Welfare Act (AWA) as amended in 1985 and Regulations in Public Law 99-198 (USDA)
3. Department of Defense Instruction 3216.01 Use of Animals in DoD Programs (SEP 2010)
4. Army Regulation (AR) 40-33 Care and Use of Laboratory Animals in DoD Programs (FEB 2005)
5. Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, 2002
6. USARIEM Policy 40-33, Institution Animal Care and Use Program (FEB 2018)

D. Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note:* For individuals whose information is publically available, provide the titles and names; for individuals whose information is not publically available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

USARIEM is a military organization with a typical direct line of authority structure. The Institute is commanded by (b)(6) (b)(6) with a Physical Therapy Degree. The Executive Officer is (b)(6) (b)(6) officer with a PhD in Exercise Physiology. USARIEM is currently composed of four research divisions and a Research Support Division. The research divisions include Biophysics and Biomedical Modeling, Military Nutrition,Military Performance, and Thermal and Mountain Medicine. The Veterinary Support and Oversight Branch (VSOB) is a branch of the Research Support Division reporting to the Executive Officer. Direction and execution of the animal care and use program is the responsibility of the Chief, VSOB, (b)(6) (b)(6) reports to the Executive Officer, USARIEM, on routine matters and has a direct line of communication to the Commander, USARIEM, on

animal related issues. (b)(6) is the Commander's principal advisor in matters of animal welfare and the animal care and use program. In addition to serving as the Chief of the VSOB, (b)(6) serves as the Institute's Attending Veterinarian (AV) on the Institutional Animal Care and Use Committee (IACUC). There are two U.S. Army trained veterinary technicians and one civilian animal care technician. A current USARIEM organization chart is enclosed. (Organizational chart – Appendix 4)

E. Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

(b)(6) Commander, USARIEM
(b)(6) Deputy Commander, USARIEM
(b)(6) Executive Officer, USARIEM
(b)(6) Chair, Institutional Animal Care and Use Committee, USARIEM
(b)(6) DVM, (b)(6) Chief, Veterinary Support and Oversight Branch, Attending Veterinarian, USARIEM
(b)(6) Director, Office of Research Quality and Compliance, USARIEM
(b)(6) Facilities Manager, USARIEM

F. Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete **Appendix 5** (Animal Usage) or provide the information requested in a similar format as an Appendix.

The major research emphasis of the Institute focuses on study of homeostatic processes, pathophysiological mechanisms, diagnosis of environmental and traumatic injuries, and nutritional disorders. Animal models are developed and used to study the effects of different extreme environmental conditions, environmental injuries in humans, blast-type injuries, and responses to nutritional manipulations. (b)(5)

(b)(5)

G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

Currently, funding for active protocols is received from a Defense Medical Research & Development Program Intramural Applied Research and Advanced Technology Development award, the Military Operational Medicine Research Program (i.e., core funding from Army HQ), and Defense Health Program-Enhanced (DHPe) appropriations. The Veterinary Support and Oversight Branch budget (b)(4) provides facility maintenance; food, water, and bedding for the animals; and husbandry

costs. Additional funds are available for animal use in research, dependent on the specific protocol being studied

H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.
Note: Questions regarding this section should be forwarded to the AAALAC Office.

None

I. Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

None

J. Note other relevant background that will assist reviewers of this report.

None

Section 2. Description

I. Animal Care and Use Program

A. Program Management

1. Program Management Responsibility [*Guide*, pp. 13-15]

a. The Institutional Official [*Guide* pp. 13-14]
Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

The Institutional Animal Care and Use Committee (IACUC) at USARIEM are appointed by Commanding Officer (b)(6) The USARIEM Commanding Officer serves as the Institutional Official (IO). After final IACUC review and approval, all research protocols and amendments, meeting minutes, semi-annual inspection reports, USDA reports, non-compliance issues, animal health and welfare concerns, and any other animal program related issues are submitted to the IO for review and final approval through the Office of Research Quality and Compliance. The Attending Veterinarian and the IACUC members have direct access to the IO at any time. The IO has an open door policy and encourages extensive communication between (b)(6) and all USARIEM division chiefs, many of who (b)(6) serves as their immediate supervisor

b. Role of the Attending Veterinarian [*Guide*, p. 14]

i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:
- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.
  Note: If preferred, this information may be provided in a Table or additional Appendix.

The Chief, Veterinary Support and Oversight Branch (VSOB) (b)(6) DVM (b)(6) serves as the full-time Attending Veterinarian (AV), providing veterinary support, consultation in laboratory animal medicine, veterinary care, research support, animal husbandry, investigator training, and review of research

protocols involving animals to ensure proper and lawful animal use. (b)(6) duties include disease detection and surveillance, prevention, diagnosis, treatment, and resolution; handling and restraint training; use of anesthetics, analgesics, and tranquilizer drugs; methods of euthanasia; surgical and post surgical care; promotion and monitoring of animal's physical and psychological well-being; overseeing adequacy of the husbandry program; and review and approval of all animal care and use via a voting role on the IACUC. (b)(6) responsible for overseeing training of institutional staff in the care and use of laboratory animals; assists in establishment and/or monitoring of occupational health and safety program; monitors for zoonotic diseases; and advises on and monitors biohazard control policies and procedures relevant to the animal care and use program. (b)(6) is a voting member of the IACUC and has direct access to the IO. One hundred percent (b)(6) time is dedicated to the animal use program.

(b)(6) DVM, (b)(6) serves as the alternate attending veterinarian in the absence of the Chief, VSOB (b)(6) assigned to the (b)(6) as a principal investigator with 25% of (b)(6) time dedicated to the VSOB to provide administrative support, program guidance, and veterinary coverage in the absence of the AV. (b)(6) also serves on the IACUC as an alternate scientist member.

ii. List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a *direct role in the provision of veterinary care* and describe their responsibilities. The Organizational Chart(s) provided in **Appendix 4** must depict the reporting relationship between these individuals and the Attending Veterinarian.
Note: If preferred, this information may be provided in a Table or additional Appendix.

The VSOB is functionally organized into the Chief (AV), two Army trained veterinary technicians, and one civilian veterinary technician. The two Army technicians are US Army Animal Care Specialists. (b)(6)

(b)(6)

The Army and civilian veterinary technicians provide the daily animal care and husbandry activities at the Institute including daily rounds of the facilities, daily health monitoring of the animals, operation of the cage wash, and feeding and watering of the animals. The civilian technician is responsible for ordering supplies and animals, tracking animal numbers for annual reports, and maintaining the VSOB calendar which provides information to PIs and facilities on room usage and procedures.

The veterinary technicians are available to provide support on research protocols when needed.

VSOB provide hands-on training to researchers and support staff under a training protocol. Basic husbandry, restraint methods, sample collection, injections, and euthanasia techniques are examples of training provided to the institute.
VSOB provides after hours animal care for the research animals used in the USARIEM research program through the use of rotating weekend duty schedules and on-call after-hours emergency contact rosters.

c. Interinstitutional Collaborations [*Guide*, p. 15]
Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

Agreements delineating roles and responsibilities are developed and signed by all collaborators. The USARIEM Office of Research & Technology Agreements (ORTA) initiates all agreements (CRDAs/MOUs/MOAs). The ORTA works directly with the PI to learn what they and their collaborators want to do or have set out in their draft Statement of Work (SOW). The type of agreement is dictated by statute and regulations. Depending on the agreement type, the ORTA may also work with the Office of Research Quality & Compliance (ORQC) or Command staff. Extramural and Intramural collaborations are covered in an IACUC policy.

Primary responsibility for animal care and use and IACUC oversight resides with the institution housing and directly using the animals. If animals will not be housed at or if animal procedures will not be performed at USARIEM facilities, the USARIEM IACUC can review the protocol at the committee's discretion. In these situations, however, the AV conducts the DoD-mandated component administrative review of the local IACUC-approved protocol and veterinary care plan and the most recent USDA inspection report (unless the institution is exempt from inspection by meeting the criteria in the Animal Welfare Act and Regulations). The AV reviews the USDA inspection reports annually for the duration of the activity. The AV may refer review to the USARIEM IACUC. For projects using dogs, cats, nonhuman primates, or marine mammals conducted at institutions not accredited by AAALAC or meeting equivalent standards, the AV is required to conduct annual site visits.

A protocol will not receive final approval from the Commander until all agreements are signed and the AV has approved

2. Personnel Management

a. Training, Education, and Continuing Educational Opportunities
Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe

how training is documented.
Note: Do not include details about the training program, which should be described in the following sections.

The IACUC oversees and evaluates training and education of all personnel involved in the ACUP. During the protocol review process, principal investigators provide qualifications and training experience for all personnel working on the research protocol. The IACUC's training policy requires all principal investigators and their staff to complete required CITI courses (Working with the IACUC, Working with Mice in Research Settings, Working with Rats in Research Settings, and Reducing Pain and Distress in Laboratory Mice and Rats. CITI training is valid for a period of 3 years and must be renewed. All new investigators and staff are required to complete the appropriate species-specific training (e.g. Rat 101) unless prior experience or training is documented and be demonstrated to a veterinarian. VSOB provides species-specific and procedure-specific training on a case by case basis. Individual training, qualifications, and experience is documented on a training matrix maintained by ORQC and training certificates and documentation is maintained in each individual's training file. During the protocol review process, the IACUC determines whether appropriate training has taken place and is also reviewed during the annual protocol review process.
Additional CITI training is available beyond the required courses and the AALAS learning library is also available for training. Continuing education opportunities are provided to research staff (on-the-job training, AALAS certification, and training courses provided by subject matter experts (b)(6) at the discretion of the PI and their respective division

i. Veterinary and Other Professional Staff [*Guide*, pp. 15-16]
For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.
Note: Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

	Name	Training/Continuing Ed	Qualifications
	(b)(6)	(b)(6) Lab Animal Residency Program, (b)(6) (b)(6) : DVM. (b)(6) (b)(6) College of Veterinary Medicine (b)(6)	(b)(6) (b)(6) Attending Veterinarian, USACEHR, Ft. Detrick, MD (b)(6) Laboratory Animal Medicine Residency (b)(6) (b)(6)

		(b)(6)	(b)(6) DVM, (b)(6) (b)(6) College of Veterinary Medicine
	(b)(6)	(b)(6) Doctor of Philosophy, Neurobiology, (b)(6) (b)(6) (b)(6) DVM, (b)(6) College of Veterinary Medicine (b)(6)	(b)(6) Doctor of Philosophy, Neurobiology, (b)(6) (b)(6) DVM, (b)(6) (b)(6) College of Veterinary Medicine

ii. Animal Care Personnel [*Guide*, p. 16]

1) Indicate the number of animal care personnel.

Three

2) Summarize their training, certification level and type, experience, and continuing education opportunities provided.

Note: If preferred, this information may be provided in a Table or additional Appendix.

Name	Training/certification/CEs	Experience
(b)(6)	(b)(6)	(b)(6) Animal Care Specialist (b)(6) (b)(6) Animal Care Specialist; USARIEM
(b)(6)	(b)(6) BS in Veterinary Sciences (b)(6)	(b)(6) provided daily clinical and husbandry care to mice and rats in USARIEM vivarium
(b)(6)	(b)(6) BA in Sociology and Anthropology (b)(6)	(b)(6) Animal Care Specialist (b)(6) (b)(6) Animal Care Specialist at USARIEM

iii. The Research Team [*Guide*, pp. 16-17; 115-116; 122; 124]

1) Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

The IACUC oversees and evaluates training and education of all personnel involved in the ACUP. During the protocol review process, principal investigators provide qualifications and training experience for all personnel working on the research protocol. The IACUC's training policy requires all principal investigators and their staff to complete required CITI courses (Working with the IACUC, Working with Mice in Research Settings, Working with Rats in Research Settings, and Reducing Pain and Distress in Laboratory Mice and Rats. CITI training is valid for a period of 3 years and must be renewed. All new investigators and staff are required to complete the appropriate species-specific training (e.g. Rat 101) unless prior experience or training is documented and be demonstrated to a veterinarian. VSOB provides species-specific and procedure-specific training on a case by case basis. Individual training, qualifications, and experience is documented on a training matrix maintained by ORQC and training certificates and documentation is maintained in each individual's training file. During the protocol review process, the IACUC determines whether appropriate training has taken place and is also reviewed during the annual protocol review process.
Additional CITI training is available beyond the required courses and the AALAS learning library is also available for training. Continuing education opportunities are provided to research staff (on-the-job training, AALAS certification, and training courses provided by subject matter experts (e.g. Charles River) at the discretion of the PI and their respective division.

a) Briefly describe the content of any required training.

CITI modules required for Investigators, Technicians (research and animal), and students working with animals must complete:
1. Investigators, Staff and Students, Working with the IACUC Basic Course,
2. Working with Mice in a Research Setting, Basic Course
3. Working with Rats in a Research Setting, Basic Course
4. Reducing Pain and Distress in Laboratory Mice and Rats, Basic Course.
5. Depending on the procedures in the approved protocol, hands-on training under the training protocol may be required prior to protocol initiation or within the framework of the protocol under supervision.

The AALAS learning library is also a resource for staff, and is allowed to substitute for required training on a case-by-case basis, as determined by the IACUC Chair. When novel or special procedures must be trained, outside expertise can be brought into the organization to train both the PI and the VSOB staff on appropriate technique under the training protocol.

The procedure is not approved for use until the AV is satisfied the appropriate level of expertise is reached by personnel conducting the procedure. Personnel also have the option of attending training workshops outside the Institute (b)(6)

Investigators, research staff, and veterinary personnel can undergo training under the Institute's training protocol. All new investigators and staff are required to complete the appropriate species-specific training (e.g. Rat 101) unless prior experience or training is documented and be demonstrated to a veterinarian

b) Describe the timing of training requirements relative to the commencement of work.

Prior to approval of animal protocols and protocol amendments, the IACUC determines whether appropriate training has been completed and is also reviewed during annual protocol review. CITI training courses must be renewed every 3 years and hands-on training is conducted/renewed at the discretion of the AV and IACUC

c) Describe continuing education opportunities offered.

Online CITI and AALAS Learning Library modules; webinars, in-house training, and appropriate workshops and conferences (e.g. PRIM&R IACUC 101, SCAW, AALAS, AVMA, (b)(6)

2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:

- who determines that personnel are qualified and trained for surgical procedures
- the roles that the Attending Veterinarian and IACUC/OB have in this determination [*Guide*, pp. 115-116]

The IACUC protocol template requires the PI to identify the surgeon. Training, credentials, and qualifications are provided in the training table of the protocol. During the initial and annual review of a protocol or amendment, the IACUC reviews this information. The AV performs a pre-review of all surgical procedures included in a protocol prior to IACUC submission and review. All personnel performing surgery on animals will receive training under the training protocol, either by the AV or a trained and competent individual in the procedure. Once training is complete, the AV will monitor the newly trained person to ensure the individual is appropriately trained and qualified to perform the procedure. The IACUC is informed the AV is confident of an individual's proficiency to perform a procedure. The

individual's training record is updated to indicate competency in the surgical procedure or related procedure. The AV has final approval on competency of all individuals working with animals

3) Describe the training and experience required to perform anesthesia. [*Guide*, p. 122]

PI and research staff receive training in the following ways: didactic, workshops, species-specific training, and/or conferences, depending on protocol requirements. Hands-on training is provided by VSOB on the training protocol. Competency is evaluated by the AV and when proficient, the individual's training record is updated appropriately. Training certificates are submitted to the AV or ORQC to update the training matrix and training folders. Veterinary technicians receive training from the AV. Competency is evaluated by the AV and when proficient, documentation occurs. Annual review by the AV is performed to ensure continued proficiency or need for refresher training.

4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [*Guide*, p. 124]

All personnel must demonstrate proficiency prior to being allowed to euthanize an animal. The AV and veterinary technicians observe personnel for proficiency. Euthanasia procedures are observed during post approval monitoring. In addition to the initial approval, annual reviews are completed which includes review of training and potential need for refresher training. The preferred method of euthanasia at USARIEM is CO2 exposure followed by thoracotomy. Alternatively, isoflurane anesthesia followed by exsanguination via cardiac stick or bilateral thoracotomy is permitted in some studies. No alternative methods are currently in use.

b. Occupational Health and Safety of Personnel [*Guide*, pp. 17-23]

i. Institutional Oversight [*Guide*, pp. 17-19]

1) List the institutional entities (units, departments, personnel, *etc.*) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists, Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.

- If contracted services are used, also include their location (e.g.,remote offices to which personnel must report).

The Natick Soldier Systems Center (NSSC) Occupational Health Clinic, USARIEM Safety Officer, and NSSC Safety Manager oversee programs that safeguard the health and safety of all personnel. During protocol and amendment review, the IACUC may request a review and recommendation/requirements from the USARIEM Safety Officer before giving final approval. An Occupational Exposure Risk Assessment form (Appendix 6) is completed by the AV, personnel and their supervisors. The risk assessment identifies potential risks to personnel entering and working in the vivarium. During the risk assessment, the AV gives the employee(s) a verbal brief on the potential risks, including allergies, impact of pregnancies and immunocompromising illnesses. Once the risk assessment form is completed, personnel go to the Occupational Health Clinic (b)(6) to schedule an occupational health assessment. The Occupational Health Clinic has two full-time occupational health nurses (b)(6) (b)(6) and a part-time occupational medicine provider (b)(6) (b)(6)

2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc. [*Guide*, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

Hazards are identified through risk assessment of the procedures and substances listed in protocols and amendments; chemicals used for cleaning and sanitation; equipment; and individual requirements (allergies, physical issues, etc). The hazards are assessed by the AV and Safety Officer and procedures are developed to manage and minimize the health effects from those hazards. The strategies for managing the hazards may include engineered methods, procedural methods, and/or recommendations/requirements based on the Occupational Health Provider's assessment. Once the best methods to manage the hazards are identified, the recommendations are written into the protocol, amendment, personnel requirements, and/or standard operating procedures.

The use and regulation of hazardous agents is managed by the installation and USARIEM safety office in consultation with the Occupational Health Clinic

and the Attending Veterinarian. Those procedures encompass regulations governing the procurement, use, storage, and disposal of all biological, chemical, and radiological agents. All USARIEM safety issues, including chemical procurement, use, storage, and chemical and biological waste disposal, are reviewed by the USARIEM and NSSC Installation Safety Officers.
All chemicals and hazardous materials brought onto the USAG-Natick for use, storage, or demonstration MUST be approved by the Directorate of Public Works-Environmental Health Office. This process is managed jointly by the USARIEM Safety Office and the USARIEM Logistics Branch. During the conduct of a study, the PI is responsible for ensuring that personnel working on the protocol practice safe laboratory procedures and that personnel are wearing the proper PPE. The AV and VSOB staff monitors the use of appropriate PPE within the vivarium and provide on-the-spot corrections and guidance as needed to ensure safety of all personnel.

There are explicit procedures required for the safe handling of any hazardous agent as outlined in the vivarium's Composite Risk Management and SOP handbook. In addition, research personnel must meet all USARIEM requirements and policies when working with hazardous agents and must train and supervise their staff in proper laboratory safety procedures. Each laboratory also has a safety monitor who is trained to ensure appropriate spill containment and the proper personnel protection equipment (PPE) is used.

The USARIEM disaster response plan (b)(5) (b)(5) covers procedures for dealing with hazardous agent spills and explains in detail the procedures for handling and reporting spills of hazardous agents. Each year the NSSC Environmental Safety Office hosts an annual, 2-day, safety-training seminar which, at a minimum, covers the following topics: hearing, blood borne pathogens, PPE use, risk assessment, and HAZCOM issues. USARIEM personnel who work with, order, or have access to any hazardous agents attend the annual training.

3) Describe methods and frequency of reassessing work-related hazards.

Hazards are identified through risk assessment of the procedures and substances listed in protocols and amendments; chemicals used for cleaning and sanitation; equipment; and individual requirements (allergies, physical issues, etc). The hazards are assessed by the AV and Safety Officer and procedures are developed to manage and minimize the health effects from those hazards. The strategies for managing the hazards may include engineered methods, procedural methods, and/or recommendations/requirements based on the Occupational Health Provider's assessment. Once the best methods to manage the hazards are identified, the

recommendations are written into the protocol, amendment, personnel requirements, and/or standard operating procedures.

The use and regulation of hazardous agents is managed by the installation and USARIEM safety office in consultation with the Occupational Health Clinic and the Attending Veterinarian. Those procedures encompass regulations governing the procurement, use, storage, and disposal of all biological, chemical, and radiological agents. All USARIEM safety issues, including chemical procurement, use, storage, and chemical and biological waste disposal, are reviewed by the USARIEM and NSSC Installation Safety Officers.
All chemicals and hazardous materials brought onto the USAG-Natick for use, storage, or demonstration MUST be approved by the Directorate of Public Works-Environmental Health Office. This process is managed jointly by the USARIEM Safety Office and the USARIEM Logistics Branch. During the conduct of a study, the PI is responsible for ensuring that personnel working on the protocol practice safe laboratory procedures and that personnel are wearing the proper PPE. The AV and VSOB staff monitors the use of appropriate PPE within the vivarium and provide on-the-spot corrections and guidance as needed to ensure safety of all personnel.

There are explicit procedures required for the safe handling of any hazardous agent as outlined in the vivarium's Composite Risk Management and SOP handbook. In addition, research personnel must meet all USARIEM requirements and policies when working with hazardous agents and must train and supervise their staff in proper laboratory safety procedures. Each laboratory also has a safety monitor who is trained to ensure appropriate spill containment and the proper personnel protection equipment (PPE) is used.

The USARIEM disaster response plan (b)(5) (b)(5) covers procedures for dealing with hazardous agent spills and explains in detail the procedures for handling and reporting spills of hazardous agents. Each year the NSSC Environmental Safety Office hosts an annual, 2-day, safety-training seminar which, at a minimum, covers the following topics: hearing, blood borne pathogens, PPE use, risk assessment, and HAZCOM issues. USARIEM personnel who work with, order, or have access to any hazardous agents attend the annual training.

4) Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [*Guide*, pp. 18-19]

Signs are posted throughout the facility with POCs and phone numbers to call regarding safety concerns, potential hazards, biohazards, and chemical emergencies.

The procedure for severe injury or illness is to dial 99-911 to request medical assistance from the Town of Natick, then dial (b)(6) (NSSC Garrison Police and Emergency Services) to report the nature and extent of the emergency and await ambulance transportation. First responders and trained personnel on-site may render the appropriate first aid while awaiting transport. If only minor first aid is required and there is no chemical contamination, personnel should be transported to the Occupational Health Clinic.

If the incident requires medical treatment beyond first aid, DA Form 285 Accident Report is filled out a soon as possible, following the incident and submitted to the USARIEM Safety Officer.

General first aid procedures are followed in the event of hazardous material contamination or acute exposure IAW local safety guidelines and laboratory SOPs

ii. Standard Working Conditions and Baseline Precautions

The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in ***subsection iii*** below.

1) Medical Evaluation and Preventive Medicine for Personnel [*Guide*, pp. 22-23] *Note:* Include blank forms used for individual health assessment as **Appendix 6.**

a) Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are ***not*** included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

All personnel participating in the Occupational Health and Safety Program receive a personal medical evaluation. This includes all Veterinary Support and Oversight Branch (VSOB) personnel and research staff (Principal Investigators, support staff, students).

b) Describe provisions for allowing an individual (following completion of individual health and job related risk assesments) to decline participation in all or part(s) of subsequently available medical and

preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.
Note: Do not include names of the personnel

Currently all personnel enrolled in the Occupational Health Program are actively participating in all aspects of the program. Personnel enrolled are those individuals who have direct contact with animals and are not exempt from participating in any aspect of the program.

c) Describe provisions for assuring confidentiality of medical information.

The Natick SSC Occupational Health Clinic follows Department of Defense Regulations and the HIPAA act to ensure medical information confidentiality. All medical records are maintained by the Occupational Health Clinic medical personnel.

d) Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open laboratories).

Contractors who may enter the vivarium for the purpose of facility maintenance are escorted at all times and required to wear appropriate PPE during their visit. Personnel are also briefed by the Veterinary Support and Oversight Branch of safety considerations and potential occupation health and safety risks before entering the vivarium .

e) Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:

- pre-employment/pre-assignment health evaluation,
- medical evaluations (including periodicity),
- diagnostic tests (e.g., for tuberculosis),
- precautions for working with potentially hazardous species (e.g., nonhuman primates, sheep, venomous species)
- immunization programs, and
- procedures for communicating health related issues.

All personnel (animal caretakers, investigators, research support staff, technicians, student employees) working with animals, with animal tissues, or in animal rooms are required to have an initial occupational health assessment physical and annual occupational health review. The Occupational Exposure Risk Assessment survey is completed by the AV and supervisor for each employee. Employees take this survey to their

Occupational Health Provider for initial assessment, recommendations, follow-up, and clearance for entering the animal facility. The survey includes a letter to be filled out and signed by provider indicating whether person is cleared for assigned duties without any special requirements or requires the use of special requirements (respirator, etc). The signed form is provided to the AV to update employee training records. An annual questionnaire is sent to employees to identify any changes to their status within the past year. The Occupational Health medical provider does a records review annually. If any significant changes to the employee's status have occurred, the Occupational Health medical provider will do an assessment to determine any changes required for the employee.

The initial occupational health assessment includes comprehensive medical history evaluations including immunization history, allergy questionnaire, other health and environmental information that may impact a person's health and ability to safely perform their job duties. TB tests are currently not included in the physical exam since we do not house non-human primates (NHPs). Immunizations are assessed and given based upon the needs of the worker and include, at a minimum, tetanus for immunizations over 10 years old. Rabies immunizations are administered by the occupational health physician if deemed necessary or if evaluation of a titer indicates that vaccination is required to maintain a safe antibody titer.

All personnel (animal caretakers, investigators, research support staff, technicians, student employees) working with animals will complete an allergy questionnaire as part of their initial assessment. Military and civilian personnel who have existing allergies to animals may be required to undergo further evaluation by the occupational health provider. Individuals who are allergic may be referred to a physician who specializes in allergies for a complete diagnostic work up. These individuals are removed from the laboratory animal environment until they are completely evaluated. At that time, a decision is made whether to allow the person to continue working with animals, to limit contact with animals, or to restrict the person from working with animals.

A similar risk assessment survey with outcome letter is given to contract employees to take to their own private physicians. The same survey includes a letter to be filled out and signed by the provider that indicates whether employee can safely enter vivarium with or without additional PPE or other devices. The risk assessment is performed annually and contractor must take to provider for review and recommendations. Outcome letter is returned to the AV and ORQC to update person's status for entry into vivarium.

f) Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

N/A

2) Personnel Training Regarding Occupational Health and Safety [*Guide*, p. 20]

Describe general educational program(s) to inform personnel about:

- allergies,
- zoonoses,
- personal hygiene,
- physical injuries in animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals),
- other considerations regarding occupational health and safety.

Include in the description a summary of the topics covered, including:

- Entities responsible for providing the training
- Frequency of training or refresher training

Note: Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

Programs for informing personnel about zoonotic diseases, personal hygiene, changes in health status (including pregnancy and immunocompromising illnesses), and other occupational health and safety related issues are covered both during the individual's annual occupational health physical, online CITI modules, and required hands-on training. New individuals are required to train on proper methods of donning and wearing of personal protective equipment (PPE) and the reasons for wearing PPE before they are allowed to enter animal rooms and/or before they are allowed to handle animals. In addition to above training, all personnel having animal contact through work related duties or research protocols are required to complete CITI modules which address zoonoses, allergies, and other occupational health issues. The NSSC holds an annual, mandatory HAZMAT training program that covers many topics, including Blood Borne Pathogens, Respirator Fit Testing, and PPE use.

3) Personal Hygiene [*Guide*, p. 20; *Ag Guide* pp. 4-5]

a) List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

Disposable PPE is provided to all personnel entering the animal facility. The PPE includes disposable laboratory overcoats, shoe covers, disposable gloves (Nitrile), facemask, and hair cover. Safety boots are provided for veterinary support personnel who clean cages and move heavy items that pose a potential injury threat. Hearing protection is located in the cage wash areas. Gloves, goggles, face mask, and face shields are available throughout the facility and are required when personnel are working with or handling hazardous agents. Personnel entering the surgery suite are provided with either scrubs or a disposable laboratory overcoat. A commercial laundry service is contracted for issued work clothing. Work issued clothing is not allowed outside the animal use area unless covered with a clean lab coat.

b) Describe arrangements for laundering work clothing.

The Logistics Section of the Research Support Division maintains a laundering program for laundry used in the vivarium (scrub tops/bottoms).

c) Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

Showers and change areas are provided (b)(6) for both female and male personnel. Shower and changing facilities (b)(6)
(b)(6)
(b)(6) All have showers, toilets, sinks, and lockers.

In addition, each of the animal rooms contain a sink for hand washing after handling rodents should the need arise.

Hand sanitizers are located at entrances and exits to the vivarium.

Work clothes are not worn outside the vivarium since there is no need to transport animals outside of the vivarium.

d) Describe policies regarding eating, drinking, and smoking in animal facilities.

Eating and drinking are permitted only in the kitchen/break room (b)(6)
(b)(6) and the administration areas (b)(6)

(b)(6) Signs are posted warning that eating or drinking is only permitted in designated areas. The USARIEM research facility is a no-smoking area. Smoking is allowed only in designated shelters outside of the facility. A smoking shelter is located (b)(6)
(b)(6)

4) Standard Personnel Protection [*Guide*, pp. 21-22]

a) Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals).

SOPs are developed for equipment used in the vivarium. Personnel review SOPs and do hands on training prior to use.

Hearing protection is available in cage wash areas. Current decibel levels reach 95-100 for a maximum of 5-10 minutes during each cycle. Due to low volume of sanitizing needs, personnel do not stay in the area for more than 5-10 minutes during a cycle. Typically only 1-2 loads are run a day so exposure is below the 8 hour standard. More often, personnel leave area as soon as cage wash is started.

Safety goggles are available and located in cage wash areas where potential splashes may occur.

A bedding dump station is located in the dirty cage wash area to prevent exposure to aerosolized rodent bedding and minimize possible allergy formation.

An eyewash station is located in the dirty cage wash area (b)(6) A first aid kit is located just outside of the kitchen/break room (b)(6) and in the clean side corridor (b)(6)

MSDS information is posted and available for employee use. Areas of risk are clearly marked outside the risk area and posted with required PPE. Wet floor and danger signs are used during hall mopping and facilities work. Tom minimize animal bites and scratches, personnel are trained to properly handle and restrain animals. Individuals are instructed to handle and properly dispose of sharp items (e.g. broken glass, syringes, needles, and scalpel blades). All compressed gas cylinders are equipped with appropriate regulators and are secured in place with chains or contained in racks.

b) Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

Rodent dander and urine; Use of PPE, HEPA-filters on microisolator lids, Dump Station for cage changing/cleaning, air exchange rates (15/hour)

c) Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

Appropriate PPE use

d) Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

The bedding dump station receives annual assessments from the Installation Industrial Hygiene officer, in addition to routine maintenance procedures. SOPs describe the proper procedures for using and maintaining the dump station. All personnel using the Dump station must read the SOP, receive hands-on training, then sign and date training sheet. Personnel requiring respirators (N95) undergo annual fit testing to ensure proper mask size.

e) Respiratory Protection

i) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

All personnel working directly or indirectly with animals receive an initial assessment and annual Occupational Health reviews. If it is determined that a person requires a respirator to safely perform duties, the Safety Office performs a mask fit test. VSOB is notified of required masks to stock and ensures that the appropriate respirators are maintained in supply inventory. Personnel requiring respirators, undergo annual fit testing to ensure proper fit of mask.

ii) Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

The Natick Soldier Systems Center (NSSC) Garrison Safety Director provides fit-testing and training in the proper use and maintenance of respirators. Training is done on initial receipt of the respirator and an annual basis.

iii) Describe how such respiratory protective equipment is selected and its function periodically assessed.

The occupational health medical provider is responsible for selecting the appropriate respiratory protective equipment. NSSC Garrison Occupational Health and Safety Office is responsible for periodic assessments and function checks for the equipment.

f) Heavy Equipment and Motorized Vehicles

i) Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

Large & Small Mechanical Cage Washer VSOB staff are the only personnel authorized to use the cage and bottle washers, bedding dump station, and water fill station. New staff are required to review all current SOPs and hands-on training is administered on an individual basis due to small number of personnel assigned to VSOB. SOPs are reviewed on a yearly basis and edited if necessary. New SOPs are developed with the addition of new equipment.

ii) List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
Note: If preferred, this information may be provided in a Table or additional Appendix.

None

iii) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal

and passenger transport.

N/A

g) Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

The surgery suite, (b)(6) utilizes multi-station rodent anesthesia machines which deliver isoflurane as the anesthetic agent. The waste gas scavenging system is an active scavenging system where waste anesthetic gases are pulled away from the animal, passed through a charcoal filter, and the filtered air is vented back into the surgery suite.

iii. Animal Experimentation Involving Hazards [*Guide*, pp. 20-21]

1) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. *Note:* If preferred, this information may be provided in a Table or additional Appendix.

a) Biological agents, *noting hazard level* (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

None

b) Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

None

c) Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

None

2) **Experiment-Related Hazard Use** [*Guide*, pp. 18-19; See also Chapters 2 and 3 in *Occupational Health and Safety in the Care and Use of Research Animals*, NRC 1997].
Note: Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents

should be available during the site visit.

a) Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

A complete description of the hazard and appropriate safety precautions must be included in the animal protocol and approved by the IACUC. Any questions the IACUC may have regarding the hazard are referred to the investigator or appropriate safety officer. The PI must be trained to use the agent and, along with VSOB staff, would be briefed by the Safety Officer on the appropriate methods and safeguards required to manage the particular agent.

All agents used are accompanied by a material safety data sheet (MSDS) and the MSDSs are available in each workspace.

(b)(5)

b) Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies) responsible for reviewing and implementing appropriate safety or containment procedures.

A complete description of the hazard and appropriate safety precautions must be included in the animal protocol and approved by the IACUC. Any questions the IACUC may have regarding the hazard are referred to the investigator or appropriate safety officer. The PI must be trained to use the agent and, along with VSOB staff, would be briefed by the Safety Officer on the appropriate methods and safeguards required to manage the particular agent.

All agents used are accompanied by a material safety data sheet (MSDS) and the MSDSs are available in each workspace.

(b)(5)

c) Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

N/A

d) Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous

agents.

Employees are risk assessed by their supervisors and attending veterinarian using the USARIEM Risk Assessment Form (Appendix 6). The form is completed by the employee's supervisor and provided to the Occupational Health medical provider during the employee's initial examinations at the Occupational Health Clinic. The Occupational Health medical provider reviews the risk assessment in relationship to the employee's medical history and determines if the employee is able to work with the hazardous material or if restrictions are required.

3) **Hazardous Agent Training for Personnel** [*Guide*, p. 20]
Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

Except for the use of isoflurane for anesthesia purposes during surgery there are no protocols using hazardous agents in animals. Should one be presented for review to the IACUC, the USARIEM and NSSC Safety Officers would be involved. Their recommendations regarding safe use, training, storage, and disposal would be incorporated into the protocol before the PI is given final approval

4) **Facilities, Equipment and Monitoring** [*Guide*, pp. 19-20]

a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and containment levels (if appropriate).
Note: If preferred, information may be provided in a Table or additional Appendix.

N/A

b) Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard containment.

N/A

c) Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

N/A

d) Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

N/A

e) Incidental Animal Contact and Patient Areas

i) List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

N/A

ii) Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

N/A

B. Program Oversight

1. The Role of the IACUC/OB [*Guide*, pp. 24-40]

a. IACUC/OB Composition and Function [*Guide*, pp. 17; 24-25]
Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 7.**

i. Describe Committee membership appointment procedures.

The Institutional Animal Care and Use Committee members at USARIEM are appointed in writing by the Commander (b)(6) also serves as the Institutional Official (IO). The IO receives and reviews recommendations from the IACUC Chair, AV, and division chiefs. In keeping with the AWA and DoD regulations, the IACUC is composed of a minimum of five people to include a Chair, the AV, a scientific member, two non-affiliated (primary and alternate), and a non-scientific member. The non-affiliated and non-scientific role can be filled by the same person. No more than three personnel are appointed from one department.

ii. Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

The IACUC usually meets once a quarter (or as often as necessary but no less than every 6 months) to review and approve new protocols, amendments, annual reviews, perform semi-annual inspections to review aspects of veterinary support and oversight and to ensure compliance with established policies, standards, and regulations.

iii. Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [*Guide*, p. 17]

New members have a one-on-one session with the IACUC Chair, the ORQC director, and the AV. They are provided a copy of the Guide for the Care and Use of Laboratory Animals and copies of all IACUC regulations and policies. These documents are also stored on the IACUC SharePoint site and on a shared drive on the USARIEM local area network.

IACUC Members and Administrative Staff are required to complete the following CITI online courses:
1. Working with the IACUC
2. Essentials for IACUC Members
3. Working with Mice in Research Settings
4. Working with Rats in Research Settings
5. Reducing Pain and Distress in Laboratory Mice and Rats

Additional training, if funding is available includes:
1. IACUC 101/201
2. SCAW IACUC Conference
3. Charles River Short Course
4. AALAS National Meeting

Online webinars and other training are considered by the IACUC after review of course content.

b. Protocol Review [*Guide*, pp. 25-27]
A blank copy of your institution's protocol review form should be provided as **Appendix 9**. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

i. Describe the process for reviewing and approving animal use. Include descriptions of how:
- the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),

- protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
- veterinary input is provided, and
- the use of animals and experimental group sizes are justified.

Note: Make sure you address each of the items above.

Each protocol must follow the standardized DoD animal use protocol format as prescribed in Army Regulation (AR) 40-33. Use of this format facilitates location of specific categories of information, which are important relative to animal use, and includes a number of "assurance statements" that must be signed by the investigator acknowledging the responsibilities for compliant research animal use. A computerized version of the DoD protocol template with detailed instructions is available for use by our PIs. (Blank DoD protocol –Appendix 7). All protocols must be approved by the PI's division chief and be reviewed by the Scientific Review Committee (SRC) and, if procedures or manipulations may cause more than slight or momentary pain or distress, by the AV prior to IACUC review. An appropriate statistical analysis regarding animal numbers must be completed and documented within the submitted protocol before final approval.

When ORQC determines that a protocol is ready for IACUC review, the Chair is notified. The Chair responds with whether to schedule the review for a convened meeting or to request Designated Member Review (DMR). An email with the protocol and supporting documents is sent to the IACUC. The email requests a convened meeting and proposes a meeting date in at least 10 working days or requests DMR process. If DMR is requested, members are given 5 full working days to call for full committee review (FCR). The call must be submitted in writing to the IACUC Chair or to the ORQC staff. If any member requests this option, a meeting is scheduled. If no member requests FCR, the Chair will assign a member to perform the DMR. No response from a member indicates the member is not calling for FCR.

The designated reviewer has the authority to approve, require modifications in (to secure approval), or request full committee review of those research projects. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review.

Procedures in the protocol that have the potential to cause pain or distress must be identified by the PI. PIs must fully describe the method or methods that will be employed to relieve or minimize the pain or distress. The PI must provide detailed justification for performing any procedure where pain or distress is caused and is not alleviated by the appropriate administration of drugs. The detailed justification must be supported scientifically. A description of the procedure alone is not sufficient scientific justification.

All protocols are reviewed by the AV to ensure that those procedures that may cause pain or distress are identified. In addition, the AV must review the methods of pain and distress alleviation to ensure they meet accepted industry standards. PIs are required to consult with the veterinarian if any procedures are likely to cause pain or distress. If indicated, criteria are formulated and the PI and AV develop a check sheet for monitoring animals to identify animals in pain or distress before they needlessly suffer. (see Appendix 14 – Animal Wellness Assessment / Intervention Scoresheet). The PI and AV determine the most appropriate method or drugs to alleviate any pain or distress. These determinations are included in the protocol for the IACUC to review and approve.

If a protocol is reviewed during a full committee meeting, the PI is invited to the meeting to provide a summary of protocol and address any protocol-specific questions that may arise. The PI is excused from the room and further discussion about the protocol occurs. After all discussion about the protocol is completed, a vote is held by the committee to approve, withhold approval, or require modifications in to secure approval. A simple majority determines the outcome. Any minority opinions are noted in the minutes of the meeting. A quorum of IACUC members is required for the review of protocols in full committee. (Minutes of two recent IACUC minutes Appendix 8)

When substantive information is lacking from a protocol, the committee may require a response from the PI. In such situations, the IACUC will vote to require modifications to secure approval and will vote on one of the following review procedures for review of the revised protocol.

(1) The committee may vote to have the revised research protocol returned for full committee review and approval at a convened meeting.

(2) The quorum of members present at the convened meeting may decide by unanimous vote to use DMR. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

The IACUC considers the criteria for review described in the regulations of the AWA, the DoD Instruction, the US Government Principles for the Utilization and Care of Vertebrate Animals in Testing, Research, and Training, PHS Policy on Humane Care and Use of Laboratory Animals, and the Guide.

Once the IACUC has made a final decision, the protocol is sent to the Institutional Official (IO) with a recommendation from the IACUC to either "Approve" or "Withhold Approval." IACUC-approved protocols may be disapproved by the Commander at his/her discretion. However, any protocol that is disapproved by the IACUC may not be approved for implementation by the Commander. The Commander is advised concerning these recommendations on the protocol in its final form. Animal use can only be conducted on approved protocols.

In accordance with AR 40-33, protocols involving the use of nonhuman primates (NHPs), dogs, cats, and marine mammals must be reviewed by next higher headquarters. Accordingly, any protocols of this nature would be reviewed by the Animal Care and Use Review Office (ACURO) at USAMRMC.

The USARIEM protocol review system requires that all animal use protocols provide the same degree of descriptive detail regardless of the current exemption status under the current Animal Welfare Act.

Ongoing studies are reviewed annually by the IACUC, starting with a list of review questions the principal investigator answers on the continuing review progress report form for each protocol. (Annual Review Form Appendix 9). Both the continuing review progress report and the protocol are reviewed by the IACUC, either by FCR or DMR according the procedure outlined above. If a protocol will still be active three years after the date of original approval, the IACUC requires a de-novo review of the entire, rewritten protocol, and it returns to Scientific Review Committee.

ii. Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description/definition of "major" vs. "minor" amendments.
Note: If preferred, this information may be provided in a Table or additional Appendix.

USARIEM policy requires that all proposed changes are reviewed and approved by the IACUC prior to implementation in the same manner as a new protocol. Initially, the Chair, IACUC, in consultation with the AV, determines if an amendment is a minor or a significant change to the protocol. Review of significant changes is handled the same as review and approval of new projects.

Significant changes include:

(1) Change in purpose or specific aim of a study (may require new protocol);
(2) Change in principal investigator;
(3) Change in species;
(4) Addition of survival surgery or switch from non-survival to survival surgery;
(5) Addition of painful procedure;
(6) Change in anesthetic agent or in the use or withholding of analgesics;
(7) Change in methods of euthanasia;
(8) Change in duration, frequency, or number of procedures performed on an animal;
(9) Change in sex of animal to be used;
(10) Need to repeat an experiment; and

(11) Additional animals that exceed the approved maximum number (Increases of <10% of the approved number of mice or rats may be considered minor, depending on the explanation).

If the amendment is classified as a minor change to the protocol, it is administratively reviewed and approved by the Chair or the Chair may delegate the administrative review to any member

Examples of minor protocol amendments include:

(1) Addition of personnel with appropriate training and Occupational Health assessment;
(2) Tissue sharing when the animal is not being euthanized solely to provide tissue; and
(3) Additional noninvasive sampling that does not result in greater discomfort, for example: weight, tape test, fecal exam.

c. Special Considerations for IACUC/OB Review [*Guide*, pp. 5; 27-33]

i. Experimental and Humane Endpoints [*Guide*, pp. 27-28]

1) Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

USARIEM has no protocols that have death as an endpoint. In the mandatory DoD protocol form, Section V.4.5. Study Endpoint, the PI must address humane criteria for removing an animal from the study, not just the endpoint for objectives.

Depending on the protocol, the IACUC would determine specific criteria on a case-by-case basis, in consultation with the AV and existing rules and regulations. Observation forms may be required to monitor each animal with approved criteria. The PI is required to perform a literature search that looks for alternatives to painful procedures and animal use. PI must specifically address and scientifically justify any proposal in which critically ill or moribund animals are allowed to die as a result of the experimental procedures without the benefits of veterinary medical treatment or early euthanasia. PI must explain the plan for the disposition of surviving animals or animals removed from the study prior to its completion.

PIs, in consultation with the AV, are required to submit monitoring forms that are reviewed and approved by the IACUC during the approval process. These monitoring forms are filled out and maintained in the PIs' laboratory notebooks.

Early or humane endpoints MUST be considered as long as the objective of the study is not jeopardized.

2) For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., pilot studies, special monitoring, other alternatives).

USARIEM has no protocols that have death as an endpoint. In the mandatory DoD protocol form, Section V.4.5. Study Endpoint, the PI must address humane criteria for removing an animal from the study, not just the endpoint for objectives.

Depending on the protocol, the IACUC would determine specific criteria on a case-by-case basis, in consultation with the AV and existing rules and regulations. Observation forms may be required to monitor each animal with approved criteria. The PI is required to perform a literature search that looks for alternatives to painful procedures and animal use. PI must specifically address and scientifically justify any proposal in which critically ill or moribund animals are allowed to die as a result of the experimental procedures without the benefits of veterinary medical treatment or early euthanasia. PI must explain the plan for the disposition of surviving animals or animals removed from the study prior to its completion.

PIs, in consultation with the AV, are required to submit monitoring forms that are reviewed and approved by the IACUC during the approval process. These monitoring forms are filled out and maintained in the PIs' laboratory notebooks.

Early or humane endpoints MUST be considered as long as the objective of the study is not jeopardized.

3) Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

During protocol review and approval, principal investigators are required to include the personnel responsible for monitoring and appropriate qualifications and credentials. Personnel are provided the appropriate training using the training protocol.

ii. **Unexpected Outcomes that Affect Animal Well-being** [*Guide*, pp. 28-29] Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-

modified animals) are identified, interpreted, and reported to the IACUC/OB.

Protocol deviations, animal welfare incidents, and unanticipated problems related to animal research procedures, treatments, and the care and well-being of research animals must be reported so they may be investigated and corrective action taken. Animals housed within the facility are monitored daily by animal care and research personnel. Animals adversely impacted by unexpected outcomes may be identified by animal care and research staff. The veterinarian is notified when the health and well-being of an animal is impacted. The veterinarian and/or PI report unexpected outcomes to the IACUC through the IACUC Chair

iii. Physical Restraint [*Guide*, pp. 29-30]

Note: This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

1) Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

IACUC policy states prolonged restraint is defined as physical restraint of a conscious animal lasting longer than 15 minutes. Prolonged restraint should be avoided unless it is essential for achieving research objectives and is specifically approved by the IACUC. Restraint procedures must be described in detail in the animal use protocol. The following information must be included in the protocol: (1) description of the restraint device, (2) duration the animal will be restrained, (3) description of how the animal will be acclimated and trained prior to procedure, and (4) description of how the animal will be observed during the procedure. Animals that fail to adapt are removed from the study and criteria for removal is developed prior to the study and reviewed and approved by the IACUC. The purpose of the restraint should be clearly explained to all personnel involved with the study. Personnel working with restrained animals must be trained in using the equipment properly and handling animals safely to cause minimal distress

2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe

- the duration of confinement
- acclimation procedures
- monitoring procedures
- criteria for removing animals that do not adapt or acclimate, and
- provision of veterinary care for animals with adverse clinical consequences.

Note: If preferred, this information may be provided in a Table or additional

Appendix.

In traumatic brain injury and post-traumatic stress disorder research, animals are immobilized in small Plexiglas tubes (Med Associates Inc.) designed for immobilization and chronic stress induction. Animals are immobilized 2 hours daily over the course of 4 days. An intervention score sheet was used to monitor animals daily. Appearance, body weight, and provoked behavior were monitored and scored. Body weights were recorded daily and animals removed from the study if greater than 10% decrease in body weight. Prolonged restraint is a component of the Single Prolonged Stress (SPS) protocol used in post-traumatic stress disorder research. Animals are immobilized in plastic train vein restraint tubes (Braintree Scientific). Animals remain in the restraint devices for 2 hours, during which time they are continuously monitored by an individual trained in performed the procedure. Individuals monitor for signs of labored breathing or cyanosis. These procedures are intended to be a stressful experience, so not acclimation is done

iv. Multiple Survival Surgical Procedures [*Guide*, p. 30]
Note: One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

Multiple major survival are permitted only under specific circumstances IAW IACUC policy. These circumstances include: (1) essential components of a single research protocol in which other methods will not achieve research goals, (2) scientifically justified by the investigator and approved by the IACUC (cost savings alone is not sufficient justification. Justification must include an explanation of the need, description of the procedure(s), total number of surgeries an animal will undergo, period of time between procedures, methods to minimize pain and distress, (3) clinically necessary for the health of the animal (determination made in consultation with the AV), (4) number of survival surgeries must be limited to the minimum number to achieve research objectives and must be determined with due consideration to minimizing pain and distress, (5) animals undergoing a major survival surgery under one protocol must be identified to prevent a second major survival surgery under a different protocol without IACUC review and approval, (6) animals that undergo a major survival surgery as part of proper veterinary care may still be used in a protocol that requires a major survival surgery in consultation with a veterinarian, (7) exceptions to the single protocol restriction for non-USDA regulated species are highly discouraged and require IACUC review and approval. The IACUC uses both the Guide and the Animal Welfare Regulations to define surgical procedures. Before the IACUC approves such protocols, the PI must clearly justify, in writing, the justification of the surgical procedures on

a scientific basis. Justification must include an explanation of the need, description of the procedure(s), total number of surgeries an animal will undergo, period of time between procedures, and methods to minimize pain and distress. Cost savings alone is not sufficient justification.

2) Summarize the types of protocols currently approved that involve multiple major survival surgical procedures

Note: If preferred, this information may be provided in a Table or additional Appendix.

None

v. Food and Fluid Regulation [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)
- methods of ensuring adequate nutrition and hydration during the regulated period

Note: If preferred, this information may be provided in a Table or additional Appendix.

None

vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances [*Guide*, p. 31]

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

For protocols with non-pharmaceutical substances listed, the IACUC requires the PI to provide a strong scientific justification and analysis of substance for approval and use. The PI must use also submit a Use of Non-Pharmaceutical Grade Substances Form (Appendix 16). PIs must use pharmaceutical grade substances, if available.

vii. Field Investigations [*Guide*, p. 32]

Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

None

viii. Animal Reuse [*Guide*, p. 5]

1) Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

None

2) Briefly describe the types of activities currently approved that involve the reuse of individual animals.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

None

3) Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.
Note: A list of specific protocols involving reuse of animals should be available during the site visit.

None

2. Post-Approval Monitoring [*Guide*, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

Post-approval monitoring of animal care and use protocols is performed to provide assurance to the IACUC that animal research is performed according to approved IACUC protocols. The PAM is performed by one or two members of the IACUC appointed by the IACUC Chair, and the AV. The PI is contacted and a time to observe scheduled protocol work is coordinated. The USARIEM IACUC Post-Approval Monitoring Checklist (Appendix 9) serves as a guide for conducting the PAM. The checklist is signed by the IACUC Chair and becomes a permanent addition to the protocol file. A summary report of PAM reviews is prepared by the IACUC Chair and reviewed by the IACUC at the next scheduled meeting where a vote is taken to approve the recommendations based on findings. All protocols undergo an annual review and complete de-novo review is conducted after 3 years from the approval of the protocol.

b. Describe the process and frequency with which the IACUC/OB reviews the program of animal care and use.

The committee performs a semi-annual facilities inspection and review of all aspects of the animal care and use program every six months. A minimum of two Committee members must perform the inspection. All committee members are encouraged to participate in inspection. The DD Form 2856 (Appendix 17) is filled out to ensure all areas of the Guide are addressed. Institutional Animal Care and Use Committee minutes include the results of the review. The completed 2856 and any discrepancies are compiled into a report which includes a plan and schedule for corrective actions and sent to the Commander for review. Corrective actions are documented in the minutes of the next meeting and sent to the Commander. A written report, signed by the majority of the IACUC members, is also maintained containing any significant findings and corrective actions. A copy of the last semi-annual report is provided (Appendix 18).

c. Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.

- Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
- If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.

Note: A copy of the last report of these reviews should be included as **Appendix 10.**

The committee performs a semi-annual facilities inspection and review of all aspects of the animal care and use program every six months. A minimum of two Committee members must perform the inspection. All committee members are encouraged to participate in inspection. The DD Form 2856 (Appendix 17) is filled out to ensure all areas of the Guide are addressed. Institutional Animal Care and Use Committee minutes include the results of the review. The completed 2856 and any discrepancies are compiled into a report which includes a plan and schedule for corrective actions and sent to the Commander for review. Corrective actions are documented in the minutes of the next meeting and sent to the Commander. A written report, signed by the majority of the IACUC members, is also maintained containing any significant findings and corrective actions. A copy of the last semi-annual report is provided (Appendix 18).

d. If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies. *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.

There have been no visits from regulatory agencies since AAALAC site visit in 2015

e. Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

None

3. **Investigating and Reporting Animal Welfare Concerns** [*Guide*, pp. 23-24]
Describe institutional methods for reporting and investigating animal welfare concerns.

(1) "Hotline" posters are placed throughout the animal facility listing the procedures for reporting potential concerns of animal abuse or violations. Reports are confidential and may be made anonymously without fear of reprisal.

(2) All allegations of animal misuse or abuse are reported to the IACUC Chair for initial review. If it is determined that there is a basis to the allegation, the Chair appoints a subcommittee to conduct an investigation and notifies the Commander. At any time during the investigation, any member of the IACUC may call for a meeting of the full Committee to discuss the complaint.
(3) All persons involved are informed of the purpose of the investigation and the manner (i.e., record review, interview, etc) in which the investigation will be conducted. Those against whom the complaint is addressed are given the opportunity to explain their side of the issue.

(4) The results of all completed investigations are reviewed by the IACUC at a convened meeting. The IACUC reviews and votes on final course of action(s).

(5) The results of the IACUC investigation and any actions taken are reported in the IACUC meeting minutes that are provided to the Commander. The Chair or designated person provides the relevant excerpt of the minutes to the reporter of the allegation (if known), individuals involved in the complaint and their Division Chief. The Commander, via ORQC, will report to the USAMRMC Animal Care and Use Review Office, AAALAC, and OLAW.

(6) All documentation will be maintained for a minimum of three years.

4. **Disaster Planning and Emergency Preparedness** [*Guide* p. 35]
Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:
- Identify those institutional components and personnel which would participate in the response.
- Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

Note: A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

The institute has an Emergency and Disaster Management Plan managed by the institute's emergency manager. The Chief, VSOB, VSOB technicians, facility manager, facility support personnel, emergency manager would participate in the response to a potential disaster or emergency. Chief, VSOB in consult with the facility manager, Principal Investigators, Division Chiefs, and Institute Commander would determine course of action for animal evacuation/relocation and priority for evacuation/relocation if warranted. A decision for euthanasia is made the Chief, VSOB after discussion with the previously identified individuals and type of research and value of animals. The VSOB NCOIC will be responsible for all husbandry requirements for the animals during the emergency/disaster situation.

II. Animal Environment, Housing and Management

Note: Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Environment

Note: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 11.**

1. Temperature and Humidity [*Guide*, pp. 43-45]

a. Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.
Note: If preferred, this information may be provided in a Table or additional Appendix.

USARIEM has a dedicated Heating Air Conditioning, Ventilation (HVAC) System (b)(6) (b)(6) The HVAC system for the animal rooms is capable of achieving specified environments as required by the research mission of the Institute and DoD research objectives. In addition, the system meets the standards as outlined by the guide, AAALAC-I, and our IACUC.

The HVAC system consists of a custom-made air-handling unit (AHU) located (b)(6) (b)(6) (b)(6) The AHU takes 100% outside air and conditions it to the following parameters:

- Summer – 49°F and 21 grains of moisture.
- Winter – 49°F and 1 grain of moisture.

During the wintertime, AHU discharge air temperature control is achieved by the stage-fired gas furnaces. During the summer time, temperature is controlled by a direct-expansion, air-cooled refrigeration unit.

The moisture content of the air leaving the AHU is controlled by a desiccant drier and a separate direct-expansion air-cooled refrigeration unit. The desiccant drier is recharged by a separate gas fired furnace.

Individual control (b)(6) is achieved by an independent combination of a steam-reheating coil and steam humidifier. This equipment allows each animal room to be individually controlled for Ambient Temperatures (Ta) within a 20-32oC (+/-1oC) range and required indoor Ambient Relative Humidity (RH) within a 30-60% (+/-5%) range.

The remainder of the vivarium facility including (b)(6) (b)(6) (b)(6) are controlled by the modified original HVAC system consisting of (b)(6) (b)(6) These AHUs take 100% outside air and heat or cool it depending upon the season. This air is automatically controlled to remain within a temperature range of 60 to 70oF.

During the winter, 100% fresh air is heated by hot water coils installed in the AHUs. During the summer, 100% fresh air is cooled by chilled water coils installed in the AHUs. Chilled water to the coil is provided by a centrifugal refrigeration chiller. Individual room temperature is achieved by the individual room steam re-heat coils. The valves in the reheat coils are designed to fail in the closed position. So, as a result, the room temperature will no longer be controlled by the reheat and gradually assume the air handler discharge temperature of 55-60°F. In addition to heating the air before entering the rooms, the air passes through a humidifier to bring the humidity to room standards.

All of the Vivarium rooms are ventilated by (b)(6) that are balanced to achieve required air distribution to the rooms.

All of the Vivarium HVAC system (Power, fans, steam, compressors, and temperature/humidity) is controlled by a digital computerized Building Management System (BMS). This system allows for the 24/7 remote monitoring and controlling of all of the conditions in each room of the vivarium and of all AHUs. The BMS is equipped with a database that allows trending and graphical representation of Ta and RH in every room. VSOB staff have access to view this system and monitor parameters and compare to readings from the secondary room devices.

VSOB staff and trained research staff monitor animal room temperature and humidity daily, noting on door chart. VSOB staff compares these secondary monitors to the BMS system and reports any discrepancies to the Facility Manager to correct.

b. List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity.
Note: If preferred, this information may be provided in a Table or additional Appendix. [*Guide*, pp. 44 and 139-140]

Mice & Rats Holding Room Temperature and Humidity Set-Points: 72°F and 40% humidity with acceptable daily fluctuations of +/- 2°F and 5% humidity.

c. Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [*Guide*, p. 43]

All cages are provided with nesting material and shelters for this purpose.

2. Ventilation and Air Quality [*Guide*, pp. 45-47]

a. Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).
Note: If preferred, this information may be provided in a Table or additional Appendix.

Forced-air ventilation supplies 100% fresh air with approximately 10-15 air changes per hour in each of the animal rooms. The pressure is highest in clean service hallways, slightly lower in the animal rooms, and lowest in the dirty service hallways. (b)(2)
(b)(2)

Detailed performance data is provided in Appendix 10.

b. Describe ventilation aspects of any special primary enclosures using forced ventilation.

None

c. If any supply air used in a room or primary enclosure is recycled, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

None

3. Life Support Systems for Aquatic Species [*Guide*, pp. 84-87]

a. Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

None

b. Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.
Note: Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 12** (Aquatic Systems Summary).

None

4. Noise and Vibration [*Guide*, pp. 49-50]
Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

Noise abatement is enhanced by keeping the animal room doors closed, placing feed in plastic barrels, and having the offices and cage washing equipment located outside of the immediate animal housing area. A door separating the clean side cage wash area from the clean corridor where the animal rooms are located significantly reduces noise in the clean corridor. All animal rooms have stainless steel, soundproof doors that remain closed. The walls are constructed of epoxy-coated concrete block with the ceiling constructed of epoxy-coated plaster. All animal cage racks and support carts have hard rubber wheels to reduce noise.

Due to the nature of some of the protocols (heat stress and behavior testing), noise abatement is essential to prevent the introduction of confounders. The facilities manager frequently communicates with PIs and VSOB staff regarding any construction or maintenance issues that need to be performed. To do this, time periods are established that allow work to be done and have minimal impact on research

B. Animal Housing (all terrestrial, flighted, and aquatic species)

1. Primary Enclosures
Note: A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries,

tanks) should be included in **Appendix 13.**

a. Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

The IACUC follows the recommendations of the Guide with regard to determining the appropriate animal cage sizes. Animal cages are solid bottom polycarbonate caging with inset wire lid. Cages are covered with a polycarbonate filter top. The wire lid is designed to contain an integrated food hopper and a slot to hold the water bottle. Rodents are provided food ad libitum using the integrated feed hopper on the wire lid. Rodents receive water from bottles with sipper tubes.

b. Describe space exceptions to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

The USARIEM uses the Guide for the Care and Use of Laboratory Animals (Guide) and AWA as a reference to determine adequate cage size and housing densities for each species of animal. Currently, USARIEM has no exceptions to the Guide

2. Environmental Enrichment, Social, and Behavioral Management [*Guide*, pp. 52-55; 63-65: *Ag Guide*, Chapter 4]

a. Environmental Enrichment

i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

All rodents are housed in solid bottom cages, metal rings for climbing, and some form of enrichment device that allows privacy (Shepherd Shacks®, CrawlBalls®, Fat Rat Huts®, etc).

ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

Rodents are housed in solid bottom cages filled with Alpha-Dri® Cob Blend (or other similar type) bedding, allowing the animals to exhibit burrowing and digging behavior. In addition, rodents are provided some combination of Nylabones®, wood blocks with holes for rodent treats for scavenging, metal rings, and/or jingle balls. Devices are protocol dependent and all approved protocols allow for species appropriate enrichment.

b. Social Environment [*Guide*, p. 64]

i. Describe institutional expectations or strategies for social housing of animals.

Rodents are group housed whenever possible and consistent with the scientific protocol underway. Rodents individually housed due to protocol requirements receive daily interaction with investigators and/or VSOB personnel. Rodents individually housed are also grouped with 10 or more conspecifics, when possible, within the same room allowing for olfactory and auditory stimulation

ii. Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for housing animals individually.

Due to the nature of research, many of the IACUC approved protocols require individual housing for each rodent to obtain consistent data via telemetry devices. Data collected using telemetry devices are based on radio frequency. An antenna board underneath the rodent cage captures the frequency emitted by the transmitter. The antenna is unable to delineate the radio frequency emitted from more than one telemetry unit. Placing two animals in the same cage would confound data collection, as the results are dependent on being able to assess individual animals which would be difficult if the rodents were group housed. These animals are provided with the appropriate environmental manipulanda/devices as described in 2.a.ii above. Other test animals are exposed to different environments and feed, so require individual housing for consistent assessment. The outcomes can be different due to individual reactions and adaptation to new feed and/or environment.

iii. Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans, environmental enrichment, etc.).

Rodents individually housed due to protocol requirements receive daily interaction with investigators and/or VSOB personnel. Rodents individually housed are also grouped with 10 or more conspecifics within the same room allowing for olfactory and auditory stimulation. Individually housed animals are provided extra environmental enrichment.

c. Enrichment, Social and Behavioral Management Program Review [*Guide*, pp. 58, 69]
Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

Social housing exceptions are regularly reviewed by the IACUC during the continuing review of the approved protocol. These programs are also reviewed and looked at during the semiannual facility inspection and program review.

d. Procedural Habituation and Training of Animals [*Guide*, pp. 64-65]
Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

Depending on protocol requirements, rodents, especially rats, may be handled daily to habituate them to the procedures of weight measuring and other minor procedures. This helps them to acclimate and experience less stress during daily activities. Protocols requiring experimental devices that may be stressful require habituation of animal to device prior to actual research procedures unless habituation would impact the objectives of the study.

e. Sheltered or Outdoor Housing [*Guide*, pp. 54-55]

i. Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

None

ii. Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

None

iii. Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

None

f. Naturalistic Environments [*Guide*, p. 55]

i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from

predation).

None

ii. Describe how food, water, and shelter are provided.

None

iii. Describe how animals are captured.

None

C. Animal Facility Management

1. Husbandry

a. Food [*Guide*, pp. 65-67]

i. List type and source of food stuffs.

The majority of rodents are fed pelleted rodent rations purchased from (b)(6) (b)(6) Alternate diets may be procured and provided on an individual protocol basis.

ii. Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:

- vendors (if more than one source, describe each)
- centralized or bulk food storage facilities if applicable
- animal facility or vivarium feed storage rooms
- storage containers within animal holding rooms

Commercial vendor storage facilities are not inspected on a regular basis. However, all feed is purchased from reputable sources that are well known throughout the laboratory animal industry. Our vendor's supply house manager (b)(6) states that all feed is produced and stored in a climate-controlled facility where the temperature never exceeds 70°F and the humidity never exceeds 55%. The vendor has a Pest Management Control program in effect to control vermin

iii. Describe special food preparation areas, such as feedmills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline

Precautions above).

None

iv. Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

Unless an approved protocol requires a different method, rodents are provided food ad libitum using the integrated feed hopper on the cage cover

v. Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

Feed is ordered and received on an as needed basis from the vendor. The date received, milling date, and expiration date are recorded on each sack. Stock is rotated so that the oldest feed is used first. Feed is stored no longer than 6 months beyond the mill date as indicated on the sack. Unused feed reaching its shelf life of 6 months is discarded. Nutritional quality of the food is checked by the manufacturer's label that is attached to the bag. Samples of feed are sent to the Army Public Health Center Food Analysis and Diagnostics Laboratory for testing, including chemical contaminants and nutritional quality.

b. Drinking Water [*Guide*, pp. 67-68]

i. Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams).

The town of Natick provides the USARIEM with potable water. Town water enters the clean cage wash area where it is purified by a reverse osmosis system and exposure to UV light to kill microorganisms.

Natick town water enters the clean cage wash area where it passes through a boost pump that is used to maintain a constant water pressure during reverse osmosis. The reverse osmosis system consists of three sub-units (system, pre-treat, and polishing loop).

The system produces between 0.5 – 1 GPM of purified water at a temperature of 54°F and includes a storage quantity of 34 gallons.

The pre-treat sub-unit includes sediment filtration, de-chlorination, and water softening and supplies the polishing loop.

The polishing loop sub-unit re-circulates at a minimum velocity of 3 ft/sec. It contains a properly sized UV sterilizer and a re-circulation pump that delivers water at a minimum flow rate of 5 GPM and a pressure between 20-60 psi. The polishing loop also includes a two-stage, absolute rated, 0.1 micron filter followed by a 0.05 micron ultra filter.

A 24 bottle filling station is used to fill rodent bottles. An ATP meter is used to test water purity once weekly.

Rodents receive water from bottles with sipper tubes.

ii. Describe methods of quality control, including monitoring for contaminants.

The VSOB monitors water quality on an annual basis. Water is tested by (b)(6) (b)(6) Water samples are tested for bacteria, heavy metals, inorganic contaminates, and volatile organic compounds. The filters and water softener cartridges are changed annually by (b)(6) during routine maintenance. The UV light is replaced annually by (b)(6) during routine maintenance. The reverse osmosis membranes are changed once every two years or earlier if water quality reports indicate that the membranes are starting to fail. Samples of feed are sent to the Army Public Health Center Food Analysis and Diagnostics Laboratory for testing, including contaminants.

iii. If automatic water delivery systems are used, describe how they are maintained and sanitized.

None

c. Bedding and Nesting Materials [*Guide*, pp. 68-69]

i. Describe type(s) and how used for various species.

Direct contact bedding for rodents consists of Alpha-Dri® cob blend (or other similar type) bedding.

ii. Describe bulk bedding storage facilities, if applicable, including vermin control measures.

None

iii. Describe quality control procedures, including monitoring for contaminants.

Bedding samples are sent to the US Army Public Health Command Food Analysis and Diagnostic Laboratory once a year. Sample are tested for chemistry and

microbiology by the laboratory including E.coli, coliforms, Salmonella, aerobic plate count, and yeast and molds. The laboratory sends the sample to an outside laboratory to test for metals

d. Miscellaneous Animal Care and Use Equipment

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

None

ii. Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

None

e. Sanitation [*Guide*, pp. 69-73]

i. Bedding/Substrate Change

1) Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

Contact Bedding: Solid-bottom cages with contact bedding are changed at least once a week to prevent ammonia buildup in microenvironment. Depending on the requirements of the protocol, they may be changed more frequently

2) Describe any IACUC/OB approved exceptions to frequencies recommended in the *Guide* or applicable regulations and the criteria used to justify those exceptions.

None

3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

A HEPA-filtered bedding dump station is used to dispose of soiled bedding. The bedding dump station is located in the dirty cage service area adjacent to the cage wash. Dirty bedding is dumped into a plastic-lined trash container located underneath the dump station during cage changing procedures. The

liner is removed when half full, tied closed, and placed in a dumpster located near the building.

Clean cages are prepared for animal use in the clean side cage wash area. Once the required number of cages is prepared, personnel move the new cages into the room(s) where the animals are housed. The animals are removed from the soiled cages and placed into clean cages. Once the cage change is completed, personnel move the soiled cages, via the door leading to the dirty corridor, to the dirty side cage wash area. Dirty cages are emptied using the HEPA-filtered bedding dump station.

ii. Cleaning and Disinfection of the Micro- and Macro-Environments
Note: A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 14** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

1) Describe any IACUC/OB approved exceptions to the *Guide* (or applicable regulations) recommended sanitation intervals.

Currently, the IACUC has no approved exceptions to the recommended procedures outlined in the Guide.

Solid bottom cages are washed and sanitized, using the mechanical cage wash 1 to 2 times a week. Water bottles and sipper tubes are washed and sanitized once a week. Wire cage lids and filter tops are washed and sanitized as needed or every 2 weeks.

Exercise devices and items used in environmental enrichment programs are sanitized every 1-2 weeks.

Cage racks and shelves are removed and sanitized each time the room is cleaned and sanitized after depopulation.

Cages, racks, and accessories are removed from the animal rooms through the dirty corridor to the dirty service area. Two mechanical cage washers are used to clean and sanitize the items. There is one large, walk-through mechanical cage and rack washer and one smaller mechanical washer used for water bottles, cage accessories, or other small loads. If necessary, heavily soiled items are first washed off over a designated area to remove as much material as possible prior to being sanitized. Items to be cleaned and sanitized are placed in the appropriate mechanical washer and the cycle is started.

2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

a) Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

The effectiveness of sanitation is assessed by using temperature-monitoring tapes, visual inspection at the end of each completed wash cycle, and computer controlled water temperature set points. Temperature monitoring tapes are placed on the rails inside the cage and bottle washers and are passed through the cage washer during the first wash cycle each day. The temperature monitoring tapes are placed in a logbook used to record the daily wash cycles. In addition, animal care personnel inspect all items after each wash cycle to ensure proper equipment operations. The cage washer is equipped with a computer that only allows the cage washer to operate once the water temperature has reached 180°F.

Microbiological monitoring is performed with the use of ATP bioluminescence. The ATP bioluminescence monitoring (systemSURE II, Hygiena, Camarillo, CA) consists of the use of a swab that is exposed to the surface or equipment in question. The swab is placed into an instrument that measures the amount of light generated. A digital display indicates the amount of ATP present and relates it to the level of contamination present on the surface in question. The ATP bioluminescence device allows for a rapid assessment of cleaning efficiency. The ATP bioluminescence device also allows for the creation of a database to track different areas of sanitation, thereby allowing for quick resolution to problem areas. ATP bioluminescence monitoring is conducted randomly on all equipment after a cage wash cycle and on all animal rooms after they have been sanitized.

b) Describe preventive maintenance programs for mechanical washers.

USARIEM facilities perform routine checks and maintenance on equipment. If there are any issues identified, a contactor provides more in-depth assessments and perform any needed service.

f. Conventional Waste Disposal [*Guide*, pp. 73-74]
Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

i. Soiled bedding and refuse.

Soiled bedding and refuse are collected in yellow trash cans located throughout the animal facility. Once weekly or as needed, full bags are tied shut and placed in a

plastic transport cart in the dirty cage wash service area. The cart is moved to the facility's central collection point and emptied into dumpsters and transported to the Natick landfill.

ii. Animal carcasses.

Animal carcasses are double bagged in red biohazard bags and stored in a freezer until disposed of by an approved private contractor

g. Pest Control [*Guide*, p. 74]

i. Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:

- monitoring devices and the frequency with which devices are checked
- control agent(s) used and where applied, and
- who oversees the program, monitors devices, and/or applies the agent(s).

The pest management program is overseen by the Installation Environmental Safety Office. Surveillance traps are placed in all rooms throughout the animal facility and are monitored weekly and replaced as needed. The insect sticky traps are maintained and checked regularly by VSOB personnel. A commercial pest control company, (b)(6) provides insect sticky traps on a monthly basis. VSOB personnel are trained to observe signs of infestation and report to the Chief, VSOB for a course of action should signs of infestation exist. If a pest problem is discovered, the commercial pest control company is contacted to evaluate and recommend the best applicable method to control and/or eliminate the vermin.

ii. Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

None

iii. Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

If the application of a pesticide is required, at least one week prior to the scheduled pesticide application date, the VSOB Chief will give a written or notice to all principal investigators housing animals in the area. The notice instructs investigators to contact the VSOB Chief if the pesticide slated for used would have an effect on their protocol.

h. Weekend and Holiday Animal Care [*Guide*, pp. 74-75]

i. Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

Veterinary Support and Oversight Branch provide veterinary support and oversight on weekends and holidays, on a rotating schedule. A monthly schedule, posted throughout the facility. All animals are checked, fed, cleaned, monitored, and treated if recovering from a surgical or experimental procedure. The attending veterinarian is available 24 hours during non-duty hours for any problems that may occur. In the absence of the attending veterinarian, the alternate attending veterinarian performs these duties. Veterinary technicians are also well trained in providing emergency veterinary treatment

ii. Indicate qualifications of weekend/holiday staff if not regular staff.

N/A

iii. Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

An on-call roster of VSOB personnel is posted on the VSOB bulletin board, in the Staff Duty Officer Book, and in multiple areas throughout the animal facility. Personnel on the call roster are should an emergency occur. This roster is updated and posted on a monthly basis. The USARIEM Vivarium Staff have been added as a special team to the installation notification system

2. Population Management [*Guide*, pp. 75-77]

a. Identification

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

Rodents are maintained in individual cages with cage cards. Information contained on cage cards is as follows: (b)(2)
(b)(2)
(b)(2) The animal ID number will be assigned when the animal first arrives at USARIEM. It will consist of the following M (for mouse) or R (for rat), 2 digit year (12, 13, 14, 15, etc.) and a number determined by arrival. So the first mouse to arrive during Fiscal Year 2015 will be identified on the cage card with the following M15-0001. The first rat would be R15-0001. Some rodents arrive with radiotelemetry devices; these numbers are noted on the cage cards.

b. Breeding, Genetics, and Nomenclature

i. Describe the program for advising investigators on the selection of animals based on genetic characteristics.

All animal models are reviewed with the investigator during protocol development and when the protocol is reviewed by the IACUC. The VSOB veterinarian is available to consult with the investigator during protocol development on specifics of laboratory animal genetics and nomenclature as necessary. The specifics of the model are also important review criteria for the IACUC. The Attending Veterinarian guides investigators in their choice of animals and corresponds with major animal providers (b)(6) to ensure genetic backgrounds will not confound study data.

ii. Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and substrain or the genetic background of all animals used in a study.

The VSOB is responsible for procurement of all research animals in the institute. Animals are ordered using the correct and complete nomenclature appropriate for the species. Animal cage cards are annotated with the complete and proper nomenclature. There is a formal manuscript review process for potential institute publications. This review process is beneficial in ensuring that animal nomenclature is properly described in the publication. The VSOB veterinarian and professional staff are available to assist scientists in the correct reporting of animals using proper nomenclature.

iii. Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including recordkeeping practices (*Guide*, pp. 75-76).

None

iv. For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, "Unexpected Outcomes that Affect Animal Well-Being."

None

III. Veterinary Care [*Guide*, pp. 105-132]

Note: Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

A. Animal Procurement and Transportation [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

Animals are procured from approved vendors with documented health monitoring programs. Vendors must provide, on request, current background information on animal production and maintenance, facilities, husbandry, veterinary care, disease surveillance and control, and personnel.

2. Transportation of Animals

Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

Transportation of animals to this facility is the responsibility of the vendor. Animals may be transported to our facility by the vendor's vehicles or a contracted agent of the vendor. Once delivered to our Institute, rodents are transported in their original shipping container by wheeled cart from the loading dock to either a quarantine room or to the investigator's assigned animal room.
When animals are transported to (b)(6)
(b)(6) they are transported through the clean hallway to the appropriate room for scheduled procedure(s).

B. Preventive Medicine

1. Animal Biosecurity [*Guide*, pp. 109-110]

a. Describe methods used to monitor for known or unknown infectious agents. Note that if sentinel animals are used, specific information regarding that program is to be provided below.

Animals are procured from licensed vendors with documented health monitoring programs. A quality assurance file is maintained on each active vendor. In addition, rodent health reports for each shipment of animals are reviewed by a veterinarian or approved VSOB staff, to confirm health status. Proper decontamination is done in

order to avoid contamination from personnel and materials, especially consumable that can serve as fomites.

b. Describe methods used to control, contain, or eliminate infectious agents.

Only animals from approved sources are allowed to enter the facility. All animal shipments are thoroughly inspected upon arrival for conformance to the contract specifications and health status by VSOB personnel. Rodents are t delivered to the investigator's assigned animal room. Rodents go through their acclimation period in the investigator's assigned animal room. Animals are held for 4-14 days for acclimation. During this time, investigators are not allowed to conduct any experimental manipulation of the animals.

No specific isolation or quarantine facility or area exists for rodents; however, each room can individually become a quarantine or isolation room. If VSOB staff suspects a potentially infectious pathogen, the room is quarantined and restricted access and decontamination procedures are instituted. Animals may be euthanized or treated and tested depending on the type and severity of the pathogen and research value of the animal.

2. Quarantine and Stabilization [*Guide*, pp. 110-111]

a. Describe the initial animal evaluation procedures for each species.

All mice and rat shipments are thoroughly inspected upon arrival for conformance to the contract specifications and health status by VSOB personnel. Animals are initially examined by the VSOB and are returned to the vendor if they do not meet contract specifications.

b. Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals, random-source animals, or both.

Purpose bred rodents arrive in filter crates equipped with a water source and appropriate feed. Crates/shipping containers are examined for structural defects and sprayed with disinfectant. Rodents are placed in cages in the receiving area and are taken to the appropriate housing room. If indicated, rodents may be quarantined in the assigned animal room for a minimum of 14 days. If no signs or symptoms of health problems have occurred, the AV may release them for study purposes. If health issues arise, select animals may be euthanized and submitted for further evaluation. All animal rooms are sanitized and disinfected before new animals enter the room.

c. Describe the required/recommended stabilization period for each species.

The stabilization period for all animals is 4-7 days prior to being released to the investigator for use. Length of time is determined by source and protocol requirements.

3. Separation by Health Status and Species [*Guide*, pp. 111-112]

a. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

There is no dedicated isolation area or room. Individual animal rooms can be designated as isolation, if needed. Ill animals are immediately evaluated by a veterinarian. Animals that show signs of an infectious disease are isolated from the healthy animals in the colony. If an entire room is believed to be exposed to an infectious agent, the group is kept intact during the process of diagnosis, treatment, and control. A necropsy is performed if an unexpected death occurs

b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

Only one rodent species is currently housed per room.

c. Describe isolation procedures and related facilities for animals.

There is no dedicated isolation area or room. Individual animal rooms can be designated as isolation, if needed. Ill animals are immediately evaluated by a veterinarian. Animals that show signs of an infectious disease are isolated from the healthy animals in the colony. If an entire room is believed to be exposed to an infectious agent, the group is kept intact during the process of diagnosis, treatment, and control. A necropsy is performed if an unexpected death occurs.

C. Clinical Care and Management [*Guide*, pp. 112-115]

1. Surveillance, Diagnosis, Treatment and Control of Disease [*Guide*, pp. 112-113]

a. Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:

- the observers' training for this responsibility
- method(s) for reporting observations (written or verbal)
- method(s) for ensuring that reported cases are appropriately managed in a timely manner.

All animals at the USARIEM are observed at least once daily (including weekends and holidays) by VSOB personnel and trained laboratory investigator staff. Information regarding the health status of potentially ill or injured animals, along with husbandry conditions, is noted on the "Daily Rounds Sheet" kept on a clipboard on the entrance door to each animal room. The Chief, VSOB is immediately informed of all ill/injured animals and/or husbandry conditions that could affect the welfare of the animals by verbal communication so the proper course of action can be taken. Ill/injured animals are noted on the room report (and medical record, if applicable) along with the diagnosis and prescribed treatment. and any noted husbandry concerns are recorded. When sick or dead animals are found, a sick call card is completed and the veterinarian and investigator are notified. On weekend and holidays, the on-call veterinarian is notified when the veterinary technician has completed rounds and if any problems are detected. Research staff may report abnormalities directly to veterinary technicians or veterinarians.

The U.S. Army uses the occupational specialty 68T to denote enlisted personnel with training as Animal Care Specialists. In addition to their basic training, the Animal Care Specialists attend an intensive 9-week training course (b)(6) (b)(6) Training consists of animal care, handling & restraint, records & identification, first aid, surgery assistance, drug administration, basic hematological and clinical laboratory techniques. Additional on-the-job training is provided once the new soldiers arrive to their duty sites. The on-the-job training provides the technicians with specialized training required for their assignment as well as training to identify abnormalities unique for the species of animals under their care.

Laboratory investigator staffs are also trained to identify abnormalities unique to the species they are working with. Since the VSOB has a limited number of staff to perform a large number of duties, the laboratory investigator staff is also trained on how to assess the health status of the animals, and perform normal routine husbandry procedures such as cage changes, feeding, and watering of the animals.

b. Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

In general, communications may take the form of email, phone calls, or in person. The AV and animal technician offices are located in the vivarium and easily accessible to researchers.

c. Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

All research animals used at USARIEM are purpose-bred animals for research and purchased from reputable vendors. Animals are accompanied by a current health report when they are shipped

2. Emergency Care [*Guide*, p. 114]

a. Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

At a minimum, animals are observed daily, seven days a week. The animal health and husbandry status, along with any adverse findings, are recorded on the daily rounds sheet and signed by a veterinary technician.

(b)(2)

(b)(2) In the event of an after-hours emergency, the PI and AV are contacted and the AV will obtain an oral description of the problem. If necessary, the AV will come in to evaluate the animal in person. In some instances, the AV may, in consultation with the PI, elect to euthanize animals that are deemed to be suffering unnecessarily and cannot be effectively treated.

b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

The AV has authority to provide treatment as needed to any animal that requires it. All attempts are made to contact the PI to explain the situation and obtain requests before any treatment is initiated. The PIs understand the importance of appropriate veterinary care and completely support the AV and VSOB staff. The IO and IACUC have authorized the veterinarian to provide treatment, including euthanasia, to minimize or alleviate pain, distress, or suffering of the animals.

3. Clinical Record Keeping [*Guide*, p. 115]

a. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

Observations and treatments for rodents are recorded on the weekly room reports, and/or on cage cards. AV and veterinary technicians use the room sheets and cage cards to record anything out of the normal, such as weight loss, skin or teeth problems and actions taken.

b. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including the IACUC/OB has access to the records.

Weekly room reports and cage cards are stored (b)(2) (b)(2) The IACUC and research staff can access these records through contact with the VSOB technicians.

c. Describe the role of the Attending Veterinarian in recordkeeping.

The AV is responsible for reviewing the records (ie. Laboratory report, necropsy report) and will sign off with initials and date after reviewing the records. VSOB technicians consult with the AV before initiating treatment or monitoring of the animals.

4. **Diagnostic Resources.** Describe available diagnostic methods used in the program including:

a. In-house diagnostic laboratory capabilities.

VSOB has the capability for minimal procedures such as fecal exams, skin scraping analysis, hematocrit, and urine analysis.

b. Commercially provided diagnostic laboratory services.

Commercial laboratories (b)(6) are used for diagnostic testing which includes rodent sera and microbiological services

c. Necropsy facilities and histopathology capabilities.

Basic necropsy services are available at USARIEM. Tissues for diagnostic histopathology examination are submitted to (b)(6) (b)(6)

d. Radiology and other imaging capabilities.

None

5. **Drug Storage and Control**

a. Describe the purchase and storage of controlled and non-controlled drugs.

All drugs are purchased through the institute's supply system. VSOB staff submit the request which list name, concentration, amount needed, vendor, and approximate cost. This is reviewed and approved by two oversight personnel and submitted to logistics for final order placement. (b)(2) (b)(2)

(b)(2)

b. Describe record keeping procedures for controlled substances.

A DA form 3949 (Controlled Substance Record) is used by veterinary personnel to the use of controlled substances. (b)(2)

(b)(2)

D. Surgery [*Guide*, pp. 115-123]

1. Pre-Surgical Planning [*Guide*, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

Presurgical planning begins during the protocol planning phase. The AV reviews the protocol prior to IACUC submission and discusses with the PI the surgical procedure, intra-operative and post-operative monitoring and care, anesthesia, analgesia, required supplies, and training requirements for the surgical team.

All major surgical procedures are scheduled with the VSOB animal care technician. The discussion includes procedures to be performed, the personnel involved, necessary equipment, estimated times required, post-surgical monitoring required, and post-operative care that will be provided and by whom. Rodent surgeries can only be scheduled by the PI listed on the approved protocol.

2. Surgical Facilities [*Guide*, pp. 116-117, 144-145]

List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:

- the type of species (including rodents, fish, agricultural species, etc.)
- nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
- the amount of use [heavy (daily), moderate (weekly), or light]
- major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
- facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery

- construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

Note: If preferred, the information requested in this section may be provided in Table.

Rodent (mice and rats) surgery is performed in the animal facility's surgical suite (b)(6) (b)(6) and managed by the AV.

(b)(2)

3. **Surgical Procedures** [*Guide*, pp. 117-118]

a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

In keeping with criteria outlined by the Guide, major surgery is considered to be those procedures that penetrate and expose a body cavity or produce substantial impairment of physical or physiological functions.

Minor survival surgery does not expose a body cavity and causes little or no physical impairment.

Currently, the surgery suite is used for large-volume rodent abdominal telemetry device implantation which is considered a major surgery since it involves an abdominal incision. This is done once on each animal.

There have been protocols in the past that required surgical blood vessel catheterization to minimize stress from frequent blood collections. These could be major or minor, depending on vessel being catheterized.

b. How is non-survival surgery defined?

A surgery in which the animal is euthanized before recovery from anesthesia. At a minimum, all non-survival surgeries are performed with the surgical site clipped and clean. Instruments and surgical area are clean and the surgeon wears clean gloves between animals if multiple non-survival surgeries are planned. Aseptic technique is maintained for the duration of procedures to ensure viability and welfare of animal during the surgery.

4. **Aseptic Technique** [*Guide*, pp. 118-119]

a. Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

Rodent survival surgeries are performed in accordance with standard aseptic technique. Aseptic technique includes surgical preparation of the patient, such as hair removal and aseptic preparation of the operative site; preparation of the surgeon, including surgical scrub, wearing aseptic surgical attire, and use of sterile gloves; sterilization of instruments, supplies, and implanted materials; and the use of operative techniques to reduce the likelihood of infection, such as maintaining a sterile field during surgery. Scrub tops or disposable surgical coats, caps, facemasks, shoe covers, and exam gloves are provided and will be donned by all support personnel who will be in the operating room during surgical procedures.

b. Describe methods used to sterilize instruments and protective clothing, including a description of approved liquid sterilants and instrument exposure time(s) required for each, if applicable.

Surgical instruments are hand cleaned, followed by ultrasonic cleaning. Instrument sets are then assembled, autoclaved, and stored in the surgery suite or in PI's laboratories. USARIEM has a steam sterilizer for use in autoclaving surgical instruments or other supplies.

During large-volume rodent surgeries, surgical instruments are cleaned and disinfected in a Nolvasan solution, rinsed with clean water, and sterilized using a glass bead sterilizer between each animal.

Effectiveness of sterilization is monitored by heat sensitive tape placed on the outside of each surgical pack, and steam sterilization indicators placed within each of the surgical packs.

Routine maintenance and calibration of the sterilization equipment is performed by medical maintenance personnel annually or when a test indicates that the sterilizer failed to perform correctly.

c. Describe methods for instrument re-sterilization between serial surgeries.

No serial surgeries are performed at USARIEM.

d. Indicate how effectiveness of sterilization is monitored.

Effectiveness of sterilization is monitored by heat sensitive tape placed on the outside of each surgical pack, and steam sterilization indicators placed within each of the surgical packs.

Routine maintenance and calibration of the sterilization equipment is performed by medical maintenance personnel annually or when a test indicates that the sterilizer failed to perform correctly.

e. Describe surgical support functions provided by the program to investigators.

VSOB technicians may assist with anesthesia, euthanasia, sample collection, procedures, and other functions as needed.

5. **Intraoperative Monitoring** [*Guide*, p. 119]
Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

Respiratory rate and effort is the main criteria monitored during rodent surgeries perform at USARIEM. Post-operative care includes assessment of motor activity, thermoregulation, breathing, ECG, blood pressure, and general appearance. Use of telemetry devices assist with this type of monitoring

6. **Postoperative Care** [*Guide*, pp. 119-120]
Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

Rodents are placed in a clean cage for recovery from any surgical procedure. Post-operative rodents are returned to their rooms of origin and are monitored until they fully recover. Post-operative monitoring of rodents is conducted by the PI's research staff trained to provide post-operative care. The VSOB animal technicians and AV are also available to provide post-operative care. Separate medical or surgical records are not maintained for rodents; however, information concerning the surgical procedures is entered in the PI's research notebook

E. Pain and Distress [*Guide*, pp. 120-121]

1. Describe how and by whom pain and distress are assessed.

The law defines a painful procedure as one that would "reasonably be expected to cause more than slight pain or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or minor procedures". The DoD protocol template requires that the PI categorize the pain level, search for alternate methods to refine or relieve potential pain inducing procedures. The AV, during protocol review, is responsible for determining the level of pain and distress that may be experienced during an experimental procedure. The AV bases this determination on established pain categorization guidelines, experience, discussion with PI, interpretation of the law, and available IACUC policies.

During implementation of the protocol, research and VSOB staff review the established criteria for assessing potential pain and distress in the animals. Depending on the protocol, check sheets are frequently part of the IACUC approval process and research staff uses these to record findings. PIs have established very specific criteria due to the nature of the protocols and staff are well-trained on what and when to report any deviations that might indicate distress.

2. Describe training programs for personnel responsible for monitoring animal well-being, including species-specific behavioral manifestations as indicators of pain and distress.

A training protocol is in place to provide personnel with training related to recognizing pain and distress in the animals. CITI modules, including Working w/ Mice, Working w/ Rats, and Reducing Pain & Distress in Laboratory Mice and Rats are also important for providing personnel with training to monitor animal well-being.

F. Anesthesia and Analgesia [*Guide*, pp. 121-123]

1. List the agents used for each species.
Note: If preferred, this information may be provided in Table or additional Appendix.

Agent	Species		Route
	Mice	Rats	
Isoflurane	X	X	inhalation
Buprenorphine	X		SQ

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

The VSOB veterinarian is a subject matter expert for the use of anesthetics and analgesics in research animals. The VSOB veterinarian consults with PIs and their staff on the use of such drugs during protocol development. Consultation with a veterinarian is required for all protocols. However, procedures that are potentially painful receive especially critical scrutiny by the VSOB veterinarian and the IACUC. Each protocol requires the VSOB veterinarian's signature indicating that the protocol was reviewed by the attending veterinarian before submission to the IACUC. In addition to reviewing painful procedures, the veterinarian also verifies that only personnel trained in the use of the appropriate drugs for the species in question are allowed to administer those drugs prior to signing or initialing the coordination block.

3. Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to

diminish pain and distress.

Anesthesia and analgesia for rodents may be given by or under the direct supervision of a principal investigator competent in the technique or by VSOB staff. Institute investigators are given training on analgesics and anesthetics by the VSOB veterinarian. Once the investigator becomes proficient in the use of the agents, they are then approved for those agents and are allowed to use them unsupervised. Additional training is made available as required

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

N/A. Paralytics are not used at USARIEM.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

The vaporizers are sent to the company once a year for maintenance to ensure proper calibration. Anesthesia machines are maintained by the Medical Maintenance section twice a year. At a minimum, the charcoal in the waste gas scavenger is replaced once a year or sooner if weight change indicates need. Individual monitoring for halogenated gases is performed once a year with specific badges by the installaiton industrial hygiene officer.

G. Euthanasia [*Guide*, pp. 123-124]

1. Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent AAALAC Reference Resources). Include:
   - consideration of species, age, condition (e.g., gestational period, or neonatal) and
   - location(s) for the conduct of the procedure.

   Note: If preferred, this information may be provided in Table or additional Appendix.

Methods of euthanasia at USARIEM for rodents include carbon dioxide or an overdose of isoflurane anesthesia followed by exsanguination and thoracotomy. Other methods of euthanasia, as described in the AVMA Guidelines on Euthanasia, may be approved by the IACUC if adequately justified in a protocol.

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

Flow meters must be attached to the CO2 cyclinders. Specific induction chambers are used for this purpose or Euthanex lids can be used with the animal's home cage. Both pieces of equipment are cleaned between animals and sanitized after use.

3. Describe the methods used to confirm death of an animal.

Rodents: Bilateral pneumothorax, cervical dislocation, decapitation, exsanguination under anesthesia

IV. Physical Plant [*Guide*, pp. 133-155]

A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

USARIEM (b)(6) is located on (b)(6) the U.S. Army Natick Soldier Systems Center in Natick, MA. The animal facility occupies (b)(6) (b)(6) The building is managed by a dedicated Building Manager under the employ of USARIEM. All animal work is done within the vivarium (b)(6) (b)(6) No animal work is done in laboratories outside the vivarium.

B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however, common features among locations or facilities may be indicated as such and do not need to be repeated.

1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
2. Physical relationship of the animal facilities to the research laboratories where animals may be used.

3. Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
4. Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).
5. Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
6. Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas incorporating fewer or additional security features than the general features described.
7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.
8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage-washing chemicals, pesticides, fuel).

Animal facilities are built on the clean/dirty corridor concept. Personnel enter the Clean Hall Way via Clean Cage Wash and then into the animal rooms. Dirty cages and other equipment exit the animal rooms (b)(6) into the Dirty hallway and are taken to Dirty Cage Wash for processing. Animals scheduled for surgery are hand-carried in their individual cages from their rooms to surgery and then returned to their rooms without leaving the clean area of the vivarium. Ancillary facilities, such as feed storage, necropsy, storage, etc., are located on the periphery of this design. No animals are maintained outside the animal rooms.

All animal work is done within the vivarium (b)(6) No animal work is done in laboratories outside the vivarium.

Finishes include:

Ceilings: Ceilings are plaster with epoxy paint.

Doors: All animal room doors are stainless steel with a plastic protection panel attached to the bottom portion.

Floors: Animal room floors are composed of a terrazzo material.

Walls: Walls are epoxy coated concrete block.

Flammable agents, if present, are placed in special flammable agent lockers and hazardous items are kept in designated rooms. Cleaning and sanitizing supplies are stored separately in a room in the dirty service area (b)(6)

(b)(2)

(b)(2)

C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17**), "Satellite Animal Housing Areas."

1. Describe the criteria used to determine/define a "Satellite Animal Housing Area," which may include remote housing facilities or laboratories temporarily or consistently housing animals.

No satellite animal housing areas exist.

2. Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

No animals are housed outside of USARIEM (b)(6)

D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

1. **Power** [*Guide*, p. 141]

For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:

- Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
- History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

(b)(2)

2. **Other System Malfunctions.** If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

None.

E. Other Facilities [*Guide*, pp. 144, 150]

1. **Other Animal Use Facilities** [*Guide*, pp. 146-150]
Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

None

2. **Other Animal Program Support Facilities**
Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

None

According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we wish to advise you that the personal data in the Program Description will become part a permanent file owned by AAALAC International, and that can be shared with AAALAC International offices and representatives in order to perform an evaluation of the institution´s animal care and use program and provide accreditation services. The institution has the option of exercising rights of data access, rectification, cancellation, and opposition at:

(b)(6)

Appendix 1: Glossary of Abbreviations and Acronyms

Abbreviation/Acronym	Definition
DD Form	Department of Defense Form
FIPR	Facility Inspection and Program Review
USARIEM	United States Army Research Institute of Environmental Medicine

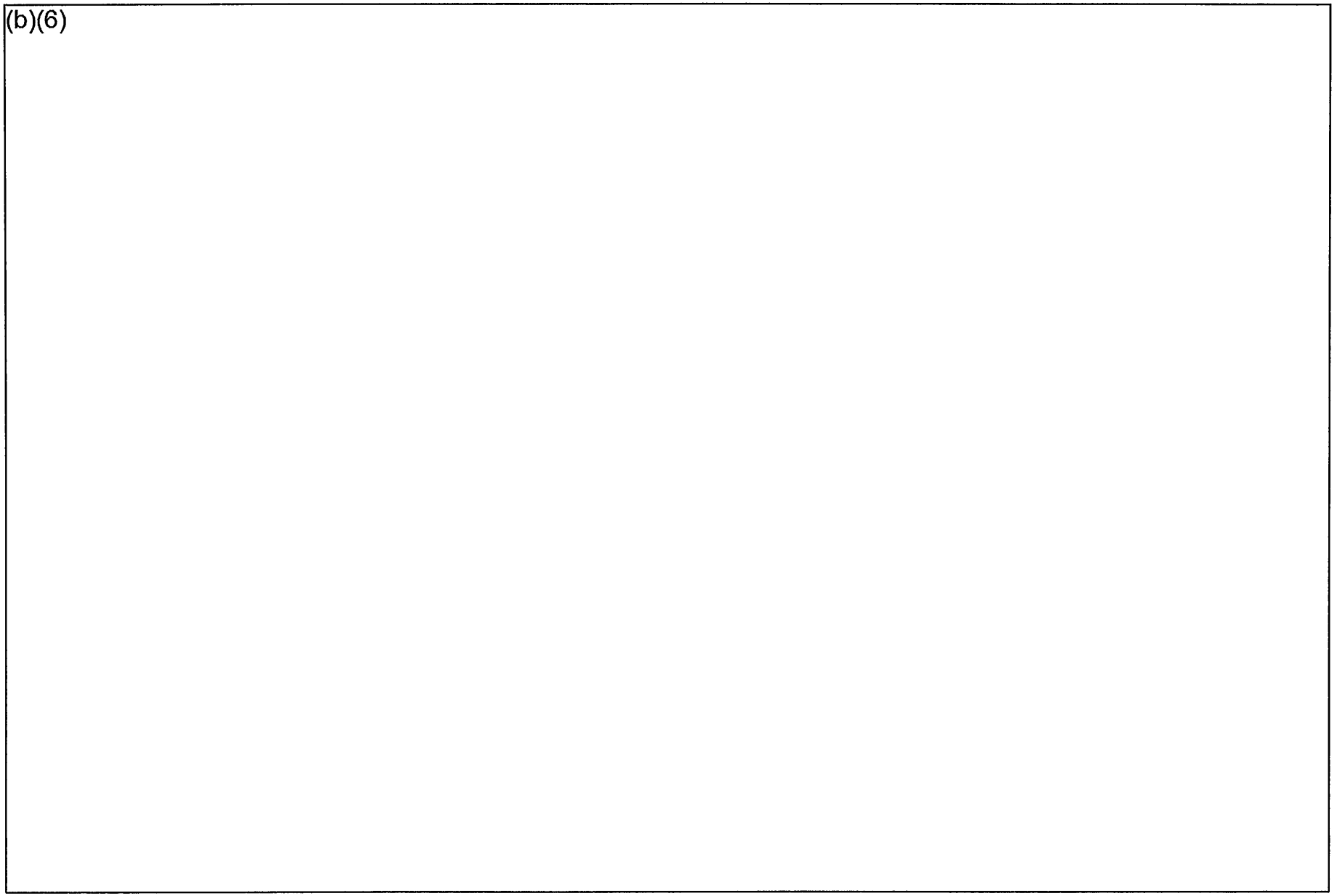
Appendix 2: Summary of Animal Housing and Support Sites

(b)(2);(b)(6)

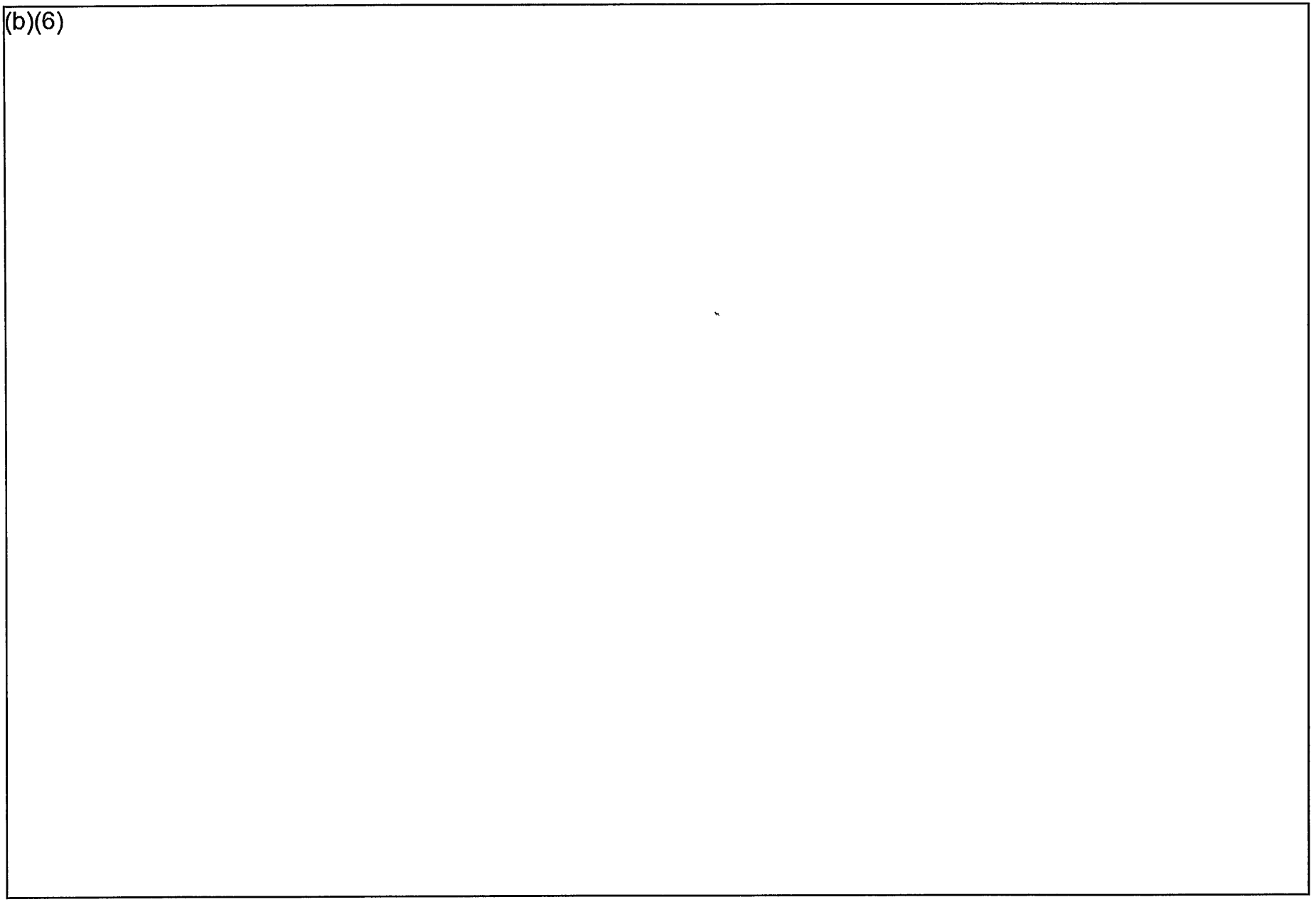
Appendix 3: Vivarium Floor Plan

(b)(2);(b)(6)

Appendix 4: Organizational Chart(s)



Appendix 4: Organizational Chart(s)



Appendix 5: Animal Usage

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

Project/Protocol Title	IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain & Distress Category (1)	Special Considerations (use checkmark if applicable)					
						SS (2)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
Manipulation of Microglial and Macrophage Phenotypes through Consumption of an Anti-inflammatory Diet in a Rat Model of Post-traumatic Stress Disorder	17-19A	(b)(6)	Rat	480	E				X		
Teaching & Training Protocol for Rodents	17-23A		Mice & Rats	150 (Mice) 150 (Rats)	C,D,E						
Effects of inflammation and hepcidin on zinc homeostasis in Mus musculus	16-21A		Mice	187	C, E						

Appendix 5: Animal Usage

(1) If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.
(2) Survival Surgery (SS)
(3) Multiple Survival Surgery (MSS)
(4) Food or Fluid Regulation (FFR)
(5) Prolonged Restraint (PR)
(6) Hazardous Agent Use (HAU)
(7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

Pain/Distress Classification Description/Definition, if applicable:

Category C: Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain-relieving drugs.
Category D: Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs.
Category E: Animals subjected to potentially painful or stressful procedures that are **not** relieved with anesthetics, analgesics and/or tranquilizer drugs. **Withholding anesthesia/analgesia must be scientifically justified in writing and approved by the IACUC.**

In the Table below, provide an approximate annual usage for all species:

Animal Type or Species	Approximate Annual Use
Rats	200
Mice	150

Animal Type or Species	Approximate Annual Use

Appendix 6: Personnel Medical Evaluation Form

USARIEM VIVARIUM OCCUPATIONAL EXPOSURE RISK ASSESSMENT

☒ Initial Enrollment	☐ Renewal	☐ Change of Status			
A. PERSONAL DATA	Last:	First:			
Status: ☐ Military ☐ Federal Civilian ☐ Other	Division:				
Potential Work Exposures Please ☒ mark for FREQUENCY of use	**NEVER**	**Several times per** Year	Month	Week	Day
B. BIOSAFETY (insert blank page as needed)					
I work with potential Bloodborne Pathogens:					
C. CHEMICAL SAFETY					
I use the following Hazardous Chemicals:					
1. Isoflurane					
2. Other notable chemical (use back if needed)					
D. RADIATION SAFETY					
I work with the following radiation hazards:					
1. X-rays (DEXA only)					

E. ANIMAL SAFETY	Mice & Rats				
	Never	Yearly	Monthly	Weekly	Daily
I. Handle Tissue, Serum, Blood, or Body Wastes					
II. Handle Dead Animals					
III. Minimal Handling (observe/transfer)					
IV. Restrains for Inoculations/Manipulations					
V. Assist/Perform Surgery/Necropsy					
VI. Perform work or inspections in the vivarium but no animal handling and minimal exposure risk					
F. MEDICAL CONDITIONS					
I have allergies that may be affected by my work environment:					

Latex? Yes ☐ No ☐	Animal(s)? Yes ☐ No ☐ List:
Are you pregnant? Yes ☐ No ☐ Are you immunocompromised? Yes ☐ No ☐	Other medical conditions not listed?

G. Personal Protective Equipment Required by Employees handling animals or working in animal rooms includes:	Labcoat☒	Surgical Mask☒	Hair Bonnet☒
	Gloves☒	Booties☒	

We certify that the above employee has received/will receive proper training and medical surveillance for any occupational exposure to the hazards listed above.

PRINT Employee's Supervisor:	Phone: (b)(6)
Supervisor's Signature:	Date:
Employee's Signature	Date:

Appendix 6: Personnel Medical Evaluation Form

USARIEM VIVARIUM OCCUPATIONAL EXPOSURE RISK ASSESSMENT

ANIMAL LABORATORY CLEARANCE

Name: _____

☐ Medically cleared with no modifications to perform assigned tasks

☐ Medically cleared but will require, at a minimum, the following additional PPE and follow-up to safely perform the assigned duties:

Faceshield	Respirator (N95)	Hearing Protection	Eye Protection
Other:			

Does the employee need **WORK MODIFICATIONS** to perform the assigned job?	Yes or No

If YES, please describe:

_____

_____

_____

_____

Does the employee need to return to you for a **FOLLOW-UP EVALUATION?** If YES, what is the DATE of the follow-up? _____	Yes or No

Description	Required	Frequency
Review Work and Medical History	Yes	Annually
Latex Allergy Screening	Yes	Annually
Immunization/Lab Review	Yes	Annually

_____ _____

Printed name of medical provider Signature

_____ _____

Phone number of medical provider Date

_____ _____

Attending Veterinarian's Signature Date

☐ After reading, asking questions, and initially my understanding of the **USARIEM Vivarium Occupational Health and Safety Program Statement** and receiving the Risk Assessment and training provided by the Attending Veterinarian, I currently decline to participate in the Occupational Health Vivarium Surveillance program.

Appendix 7: IACUC/OB Membership Roster

|

US Army Research Institute of Environmental Medicine (USARIEM)
INSTITUTIONAL ANIMAL CARE & USE COMMITTEE (IACUC) MEMBERSHIP

Primary Members						
Rank/ Title	Last Name	First Name	Earned Degrees	Affiliation	Position Title	PHS Policy Membership Requirement
(b)(6)					Research Physiologist	Scientist, Chair
					Attending Veterinarian	Veterinarian
					Agreements Manager/Quality Management Officer	Non-Scientist
					Research Physiologist	Scientist
					Outreach Services Coordinator	Non-Scientist/Non-Affiliated
					Research Physiologist	Scientist, Vice Chair
Alternate Members						
Rank/ Title	Last Name	First Name	Earned Degrees	Affiliation	Position Title	PHS Policy Membership Requirement
(b)(6)					Records Manager; Library Technician	Non-Scientist/Non-Affiliated
					Alternate Attending Veterinarian, Research Physiologist	Veterinarian
Member-in-Training						
(b)(6)					ORISE Program Coordinator	Scientist

Appendix 8: IACUC/OB Minutes

DEPARTMENT OF THE ARMY
US ARMY RESEARCH INSTITUTE OF ENVIRONMENTAL MEDICINE
(b)(6)
NATICK, MASSACHUSETTS 01760-5007

MCMR-EMZ-A

31 January 2018

MEMORANDUM FOR RECORD

SUBJECT: Minutes of the US Army Research Institute of Environmental Medicine (USARIEM) Institutional Animal Care and Use Committee Meeting on 13 October 2017

Members Present:

(b)(6)	Acting Chair/ Vice Chair, Scientist (b)(6) USARIEM Attending Veterinarian, (b)(6) USARIEM Nonscientist, Nonaffiliated, Natick, MA Scientist and Alternate Attending Veterinarian, (b)(6) USARIEM Scientist, (b)(6) USARIEM

Voting Member Absent:

(b)(6)	Nonscientist, (b)(6) USARIEM Chair (b)(6) USARIEM

Administrative Staff:

(b)(6)	(b)(6) USARIEM USARIEM USARIEM

1. The IACUC convened (b)(6) 13 October 2017. The Acting Chair confirmed a quorum of five voting members, to include one nonaffiliated member and a veterinarian, at 1000.

2. RECUSALS: (b)(6) was recused from the vote as he is the Principal Investigator (PI) of the protocol 17-19-A.

3. (b)(6) informed the committee that he would be taking a temporary assignment that would take him away from USARIEM for a period of time.

4. SEMI-ANNUAL FACILITY INSPECTION AND PROGRAM REVIEW (FIPR):

a. Deficiencies from the previous FIPR in March 2017 were determined to be corrected.

Appendix 8: IACUC/OB Minutes

MCMR-EMZ
SUBJECT: Minutes of the USARIEM Institutional Animal Care and Use Committee Meeting on 13 October 2017

b. (b)(6) discussed the findings from the semi-annual facilities inspection checklist. No significant deficiencies were found and six minor deficiencies were noted on that checklist. These minor findings, as listed in the FIPR, were discussed and the IACUC agreed to the findings and the proposed corrections and suspense dates.

c. (b)(6) discussed findings from the program review. No significant findings resulted from the review but she noted three minor deficiencies. These minor findings, as listed in the FIPR, were discussed and the IACUC agreed to the findings and the proposed corrections and suspense dates.

5. REVIEW OF PI RESPONSE: 17-19-A, *Manipulation of Microglial and Macrophage Phenotypes through Consumption of an Anti-inflammatory Diet in a Rat Model of Post-traumatic Stress Disorder*, PI: (b)(6)

a. (b)(6) briefly summarized the results of his experiment in which he collected whole brains from two rats via protocol 17-23-A, Teaching and Training Protocol Using Rodents. Using samples from these collected tissues, he tested his tissue processing methods for protocol 17-19-A. As described in his report which was sent to the IACUC on 22 September 2017, he was able to generate sufficient biomass to achieve the objectives of the experiment which were to collect microglia and isolate RNA for generating cDNA and subsequent quantitative PCR.

(b)(6) *departed at 1051 hours*

b. DISCUSSION:

(b)(5)

Appendix 8: IACUC/OB Minutes

MCMR-EMZ
SUBJECT: Minutes of the USARIEM Institutional Animal Care and Use Committee Meeting on 13 October 2017

(b)(5)

MOTION: Require modifications as listed above to secure approval.

VOTE TOTAL: 5; FOR: 5, OPPOSED: 0, ABSTAINED: 0

The IACUC agreed that should all modifications be made appropriately, the protocol could be reviewed subsequent to the meeting via Designated Member Review.

6. ADJOURN

The meeting adjourned on October 13, 2017 at 1129.

Acknowledged

(b)(6)

Commanding

Appendix 8: IACUC/OB Minutes

DEPARTMENT OF THE ARMY
US ARMY RESEARCH INSTITUTE OF ENVIRONMENTAL MEDICINE
(b)(6)
NATICK, MASSACHUSETTS 01760-5007

MCMR-EMZ-A

31 January 2018

MEMORANDUM FOR RECORD

SUBJECT: Minutes of the US Army Research Institute of Environmental Medicine (USARIEM) Institutional Animal Care and Use Committee (IACUC) Special Meeting on 17 August 2017

Members Present:

(b)(6)

Acting Chair/Vice Chair, Scientist (b)(6) USARIEM (by phone)
Attending Veterinarian, (b)(6) USARIEM
Nonscientist, (b)(6) USARIEM

Alternate Member Present:

(b)(6)

Scientist and Alternate Attending Veterinarian, (b)(6) USARIEM

Member-in-Training:

(b)(6)

Scientist, (b)(6) USARIEM

Administrative Staff:

(b)(6)

(b)(6) USARIEM
USARIEM
USARIEM

1. The IACUC convened (b)(6) 17 August 2017 at 1300h. The Vice Chair confirmed that there was no quorum and that this was a special meeting of the IACUC being conducted in accordance with IACUC Policy #1.

2. RECUSALS: None.

3. The Vice Chair explained that this meeting was called to hear the report from the subcommittee formed to investigate a potential deviation and report of potential misuse/abuse of animals in protocol 16-03-A, Principal Investigator (PI): (b)(6) (b)(6) The Vice Chair asked for (b)(6) to give the board an explanation of what had transpired since the subcommittee was formed during the 1 August 2017 IACUC meeting.

4. DISCUSSION:

Appendix 8: IACUC/OB Minutes

MCMR-EMZ
SUBJECT: Minutes of the USARIEM Institutional Animal Care and Use Committee Meeting on 17 August 2017

(b)(5)

g. The members reviewed the subcommittee recommendations from the 8 August 2017 memo on a paragraph-by-paragraph basis. The members agreed with the recommendations. (b)(6) a new PAM policy which could be sent to the IACUC and would instruct on how to do the PAM for this protocol.

(b)(5);(b)(6)

5. ADJOURN:

Appendix 8: IACUC/OB Minutes

MCMR-EMZ
SUBJECT: Minutes of the USARIEM Institutional Animal Care and Use Committee Meeting on 17 August 2017

The meeting adjourned on August 17, 2017 at 1250.

Acknowledged
(b)(6)

Commanding

Appendix 9: IACUC/OB Protocol Form

DOD ANIMAL USE PROTOCOL FORMAT

READ THESE INSTRUCTIONS.

(THEY WILL MAKE YOUR LIFE EASIER.)

Requirements: All DOD animal use protocols must utilize the following format as presented in AR 40-33. This protocol format includes requirements of the Animal Welfare Act Regulations, the Guide, and other applicable Federal regulations and DOD directives.

DoD animal use protocol format: The following template is a "fill-in-the-blank" type of document. Embedded within the template as BLUE hidden text are detailed written explanations and instructions.

To see the hidden text, click on the Home tab of the Ribbon, in the Paragraph block of commands, click on the paragraph symbol (¶). To hide the formatting symbols and hidden text, simply click the same button again. An example of help text is located just below. You can also make a check in the Hidden Text check box by clicking on the Office button and selecting <Word Options>, select "display," and check "Hidden Text" under 'Always show these formatting marks on the screen.'

BLUE text will not normally print.

Each paragraph and subparagraph in the template must have a response. Title headings do not require a response. Portions of the protocol format that are not applicable will be marked "N/A." There are no space limitations for the responses. Pertinent standing operating procedures or similar documents that are readily available to the IACUC may be referenced to assist in the description of specific procedures.

Protocol Cover Sheet: Before the protocol is submitted for IACUC review, at least three signatures are required on the protocol cover sheet, provided as a separate, scanned document. They must include those of the

1. Principal Investigator (PI),
2. Scientific Review Committee chair or vice chair (This signature verifies that the animal use proposal received appropriate scientific peer review and is consistent with good scientific practice. In addition, a person knowledgeable in statistics has reviewed the protocol and ensured that the number of animals used is appropriate to obtain sufficient data and is not excessive, and the statistical design is appropriate for the intent of the study.), and
3. Attending or Consulting Veterinarian. (The Animal Welfare Act Regulations require that an attending veterinarian must be consulted in the planning of procedures/manipulations that may cause more than slight or momentary pain or distress, even if relived by anesthetics or analgesics. In addition, verifies that the Veterinary Support & Oversight Branch has assisted with the coordination for veterinary support to the study.)

The signed cover sheet is submitted only with the initial IACUC protocol submission.

Appendix 9: IACUC/OB Protocol Form

PROTOCOL TITLE: *Title must include the common name, genus and species of the animal(s) used in research.*

PRINCIPAL INVESTIGATOR: *Include Title, Department/Division, Phone, and E-mail address.*

CO-INVESTIGATOR(S): *Include Title, Department/Division, Phone, and E-mail address.*

I. NON-TECHNICAL SYNOPSIS:

II. BACKGROUND:

II.1. Background:

II.2. Literature Search for Duplication: *List the databases searched for unnecessary duplication. A search of either the Research Portfolio Online Reporting Tools (RePORT) database (http://projectreporter.nih.gov/reporter.cfm), or the Federal Research in Progress (FEDRIP) database is required. FEDRIP is now an EBSCO database service available through MyAthens (https://login.openathens.net/auth?t=%2Flogin%3Fr%3Dhttps%253A%252F%252Fauth.athensams.net%252F%253Fath_returl%253D%252522%25252Fmv%25252F%252522%2526ath_dspid%253DATHENS_MY&ctx=dsc). An additional search of the scientific literature (MEDLINE, PUBMED, MEDLARS, AWIC, etc) is highly recommended.*

II.2.1. Literature Source(s) Searched:

II.2.2. Dates of Searches:

II.2.3. Period of Searches:

II.2.4. Key Words of Searches:

II.2.5. Results of Searches: *Provide a narrative description of the results of the literature search. The description should include a statement to the effect that the research is not duplicative; or, if it is duplicative, the justification for performing the duplicative work.*

III. OBJECTIVE/HYPOTHESIS:

IV. MILITARY RELEVANCE:

V. MATERIALS AND METHODS:

V.1. Experimental Design and General Procedures:

V.1.1. Experiment 1:

V.1.2. Experiment 2:

Appendix 9: IACUC/OB Protocol Form

V.2. Data Analysis and Animal Number Justification:

V.3. Laboratory Animals Required and Justification:

V.3.1. Non-animal Alternatives Considered:

V.3.2. Animal Model and Species Justification:

V.3.3. Laboratory Animals:

V.3.3.a. Genus and Species:

V.3.3.b. Strain/Stock: If inbred or specialized animals are required, use proper terminology. (Veterinary Support and Oversight Branch (VSOB) personnel will provide complete nomenclature for inbred strains and outbred stocks of rodents.)

V.3.3.c. Source/Vendor:

V.3.3.d. Age: *Age range is acceptable.*

V.3.3.e. Weight: *Weight range is acceptable,*

V.3.3.f. Sex: *Specify either male or female, but not "either". If both sexes will be used, specify animal numbers for each.*

V.3.3.g. Special Considerations:

V.3.4. Number of Animals Required (By Species):

V.3.5. Refinement, Reduction, Replacement (3Rs):

V.3.5.1. Refinement:

V.3.5.2. Reduction:

V.3.5.3. Replacement:

V.4. Technical Methods:

V.4.1. Pain/Distress Assessment:

V.4.1.1. Pain Category (APHIS Form 7023):

V.4.1.1.1. No Pain: ___(# of animals) (Column C).

V.4.1.1.2. Alleviated Pain: ___(# of animals) (Column D).

Appendix 9: IACUC/OB Protocol Form

V.4.1.1.3. Unalleviated Pain or Distress: ___(# of animals) (Column E).

V.4.1.2. Pain Relief/Prevention:

V.4.1.2.1. Anesthesia/Analgesia/Tranquilization:

V.4.1.2.2. Pre- and Post-procedural Provisions:

V.4.1.2.3. Paralytics:

V.4.1.3. Literature Search for Alternatives to Painful or Distressful Procedures:

V.4.1.3.1. Sources Searched: *Most databases may be accessed at* http://www.nal.usda.gov/awic

V.4.1.3.2. Date of Search:

V.4.1.3.3. Period of Search:

V.4.1.3.4. Key Words of Search:

V.4.1.3.5. Results of Search:

V.4.1.4. Unalleviated Painful/Distress Procedure Justification:

V.4.2. Prolonged Restraint:

V.4.3. Surgery:

V.4.3. 1. Pre-surgical Provisions:

V.4.3.2. Procedure:

V.4.3.3. Post-surgical Provisions:

V.4.3.4. Location:

V.4.3.5. Surgeon:

V.4.3.6. Multiple Major Survival Operative Procedures:

Appendix 9: IACUC/OB Protocol Form

V.4.3.6.1. Procedures:

V.4.3.6.2. Scientific Justification:

V.4.4. Animal Manipulations:

V.4.4.1. Injections:

V.4.4.2. Biosamples:

V.4.4.3. Adjuvants:

V.4.4.4. Monoclonal Antibody (MAbs) Production

V.4.4.5. Animal Identification:

V.4.4.6. Behavioral Studies:

V.4.4.7. Other Procedures:

V.4.4.8. Tissue Sharing:

V.4.5. Study Endpoint:

V.4.6. Euthanasia:

V.5. Veterinary Care:

V.5.1. Husbandry Considerations:

V.5.1.1. Study Room:

V.5.1.2. Special Husbandry Provisions:

V.5.1.3. Exceptions:

Appendix 9: IACUC/OB Protocol Form

V.5.2. Veterinary Medical Care:
V.5.2.1. Routine Veterinary Medical Care:

V.5.2.2. Emergency Veterinary Medical Care

V.5.3. Environmental Enrichment:
V.5.3.1. Enrichment Strategy:

V.5.3.2. Enrichment Restriction:

VI. STUDY PERSONNEL QUALIFICATIONS AND TRAINING:

NOTE: A "Study Personnel Qualifications and Training Table" must be included under this section and contain the below described four column headings:

STUDY PERSONNEL QUALIFICATIONS and TRAINING

Name of Activity or Procedure	Name of person performing the procedure	Qualifications or Experience with the proposed species	Training
e.g., Venous Catheterization of dogs	Joe Blow	Assistant Lab animal tech (ALAT) with 2 years experience.	API Tech college. Canine procedures workshop, 2005 .
e.g., Tail vein injection in rats	Josephine Bleu	Performed tail vein injections in ≥200 mice	Trained to do injections by PI on protocol 11-04-A

VII. BIOHAZARD/SAFETY:

Biological wastes to include needles, syringes, and blood, serum or plasma containing glass test tubes will be packaged and shipped off-site to a commercial company for disposal while blood-contaminated materials and plastic pipette tips will be bagged and stored in the hazardous waste cooler until incinerated or disposed of by an approved private contractor. Animal carcasses and tissues will be double bagged and stored in a freezer until disposed of by an approved private contractor. All chemical waste will be identified and brought to the Central Chemical Facility. All personnel in the laboratory are, or will be, trained in the use and disposal of such chemicals and complete Waste Management and Laboratory Safety Courses.

VIII. ENCLOSURES:

Appendix 9: IACUC/OB Protocol Form

At the discretion of the PI unless directed by the IACUC, list below and provide as separate documents enclosures, such as results of any literature searches, laboratory SOPs or IACUC policies on adjuvants, monoclonal antibody production, tissue sharing, food and/or water restriction, prolonged restraint, and pathology addenda, pain assessment criteria or animal monitoring checklists.

Are you proposing to use a non-pharmaceutical grade substance in your project?

No☐

Yes☐ If yes, complete and submit with this protocol the IACUC Protocol Addendum Form 1: *Use of Non-Pharmaceutical-Grade Chemicals and Other Substances* to describe and justify and obtain IACUC approval for use. View hidden text for definition of pharmaceutical-grade substance

IX. ASSURANCES The law specifically requires several written assurances from the Principal Investigator. These assurances are statements which must be provided as a separate document. Download, read and sign the assurance statements, as applicable, in the document named *Investigator Assurances_Animal Research*, scan and submit with the completed protocol.

X. BIBLIOGRAPHY:

1.

Appendix 10: IACUC/OB Periodic Report

DOD SEMIANNUAL PROGRAM REVIEW/ FACILITY INSPECTION CHECKLIST

ORGANIZATION	DATE OF REVIEW (YYYYMMMDD)
US Army Research Institute of Environmental Medicine	20170919

Completion of this checklist by the IACUC during the semi-annual program review and facility inspection is mandatory. Mark X in the most appropriate category for each item. KEY: A = Acceptable; M = Minor deficiency; S = Significant deficiency (is or may be a threat to animal health or safety). Reference The Guide for the Care and Use of Laboratory Animals, 8th edition, for category details.

CATEGORIES	A	M	S	N/A
SECTION I - ANIMAL CARE AND USE PROGRAM				
1. PROGRAM MANAGEMENT				
a. PROGRAM MANAGEMENT RESPONSIBILITY	X			
(1) The Institutional Official	X			
(2) The Attending Veterinarian	X			
(3) The Institutional Animal Care and Use Committee	X			
(4) Collaborations	X			
b. PERSONNEL MANAGEMENT		X		
(1) Training and Education		X		
(a) Veterinary and Other Professional Staff	X			
(b) Animal Care Personnel	X			
(c) The Research Team		X		
(d) The IACUC		X		
(2) Occupational Health and Safety of Personnel	X			
(a) Control and Prevention Strategies	X			
(b) Hazard Identification and Risk Assessment	X			
(c) Facilities, Equipment, and Monitoring	X			
(d) Personnel Training	X			
(e) Personal Hygiene	X			
(f) Animal Experimentation Involving Hazards	X			
(g) Personal Protection	X			
(h) Medical Evaluation and Preventive Medicine for Personnel	X			
(3) Personnel Security	X			
(4) Investigating and Reporting Animal Welfare Concerns	X			
2. PROGRAM OVERSIGHT				
a. THE ROLE OF THE IACUC	X			
(1) IACUC Constitution and Function	X			
(2) Protocol Review		X		
(3) Special Considerations for IACUC Review		X		
(a) Experimental and Humane Endpoints		X		
(b) Unexpected Outcomes		X		
(c) Physical Restraint		X		
(d) Multiple Survival Surgical Procedures		X		
(e) Food and Fluid Regulation		X		
(f) Use of Non-Pharmaceutical Grade Chemicals and Other Substances	X			
(g) Field Investigations				X
(h) Agricultural Animals				X
b. POSTAPPROVAL MONITORING	X			
3. DISASTER PLANNING AND EMERGENCY PREPAREDNESS	X			
SECTION II - ENVIRONMENT, HOUSING, AND MANAGEMENT				
4. TERRESTRIAL ANIMALS - ENVIRONMENT				
a. MICROENVIRONMENT AND MACROENVIRONMENT	X			
b. TEMPERATURE AND HUMIDITY	X			
c. VENTILATION AND AIR QUALITY	X			
d. ILLUMINATION	X			
e. NOISE AND VIBRATION		X		

Appendix 10: IACUC/OB Periodic Report

CATEGORIES	A	M	S	N/A
SECTION II - ENVIRONMENT, HOUSING, AND MANAGEMENT *(Continued)*				
5. TERRESTRIAL ANIMALS - HOUSING				
a. MICROENVIRONMENT (PRIMARY ENCLOSURE)	X			
b. ENVIRONMENTAL ENRICHMENT	X			
c. SHELTERED OR OUTDOOR HOUSING				X
d. NATURALISTIC ENVIRONMENTS	X			
e. SPACE	X			
(1) General Considerations for All Animals	X			
(2) Laboratory Rodents	X			
(3) Other Common Laboratory Animals				X
(4) Nonhuman Primates				X
(5) Agricultural Animals				X
6. TERRESTRIAL ANIMALS - MANAGEMENT				
a. BEHAVIORAL AND SOCIAL MANAGEMENT	X			
(1) Activity	X			
(2) Social Environment	X			
(3) Procedural Habituation and Training of Animals	X			
b. HUSBANDRY	X			
(1) Food	X			
(2) Water	X			
(3) Bedding and Nesting Materials	X			
(4) Sanitation	X			
(a) Bedding/Substrate Change	X			
(b) Cleaning and Disinfection of the Microenvironment	X			
(c) Cleaning and Disinfection of the Macroenvironment	X			
(d) Assessing the Effectiveness of Sanitation	X			
(5) Waste Disposal	X			
(6) Pest Control	X			
(7) Emergency, Weekend, and Holiday Care	X			
c. POPULATION MANAGEMENT	X			
(1) Identification	X			
(2) Recordkeeping	X			
(3) Breeding, Genetics and Nomenclature	X			
7. AQUATIC ANIMALS - ENVIRONMENT				
a. MICROENVIRONMENT AND MACROENVIRONMENT				X
b. WATER QUALITY				X
c. LIFE SUPPORT SYSTEM				X
d. TEMPERATURE, HUMIDITY, AND VENTILATION				X
e. ILLUMINATION				X
f. NOISE AND VIBRATION				X
8. AQUATIC ANIMALS - HOUSING				
a. MICROENVIRONMENT (PRIMARY ENCLOSURE)				X
b. ENVIRONMENTAL ENRICHMENT AND SOCIAL HOUSING				X
c. SHELTERED, OUTDOOR, AND NATURALISTIC HOUSING				X
d. SPACE				X
9. AQUATIC ANIMALS - MANAGEMENT				
a. BEHAVIORAL AND SOCIAL MANAGEMENT				X
b. HUSBANDRY				X
(1) Food				X
(2) Water				X
(3) Substrate				X
(4) Sanitation				X
(a) Cleaning and Disinfection of the Macroenvironment				X
(5) Waste Disposal				X
(6) Pest Control				X
(7) Emergency, Weekend, and Holiday Care				X
c. POPULATION MANAGEMENT				X
(1) Identification				X
(2) Aquatic Animal Recordkeeping				X

DD FORM 2856, MAY 2012 Page 2 of 4 Pages

Appendix 10: IACUC/OB Periodic Report

CATEGORIES	A	M	S	N/A
SECTION III - VETERINARY CARE				
10. ANIMAL PROCUREMENT AND TRANSPORTATION				
a. ANIMAL PROCUREMENT	X			
b. TRANSPORTATION OF ANIMALS	X			
11. PREVENTIVE MEDICINE				
a. ANIMAL BIOSECURITY	X			
b. QUARANTINE AND STABILIZATION	X			
c. SEPARATION BY HEALTH STATUS AND SPECIES	X			
d. SURVEILLANCE, DIAGNOSIS, TREATMENT, AND CONTROL OF DISEASE	X			
12. CLINICAL CARE AND MANAGEMENT				
a. MEDICAL MANAGEMENT	X			
b. EMERGENCY CARE	X			
c. RECORDKEEPING	X			
13. SURGERY				
a. TRAINING	X			
b. PRESURGICAL PLANNING	X			
c. SURGICAL FACILITIES	X			
d. SURGICAL PROCEDURES	X			
e. ASEPTIC TECHNIQUE	X			
f. INTRAOPERATIVE MONITORING	X			
g. POSTOPERATIVE CARE	X			
14. PAIN AND DISTRESS	X			
15. ANESTHESIA AND ANALGESIA	X			
16. EUTHANASIA	X			
SECTION IV - PHYSICAL PLANT				
17. GENERAL CONSIDERATIONS	X			
18. FUNCTIONAL AREAS		X		
19. CONSTRUCTION GUIDELINES				
a. CORRIDORS	X			
b. ANIMAL ROOM DOORS	X			
c. EXTERIOR WINDOWS	X			
d. FLOORS		X		
e. DRAINAGE	X			
f. WALLS AND CEILINGS	X			
g. HEATING, VENTILATION, AND AIR CONDITIONING	X			
h. POWER AND LIGHTING	X			
i. STORAGE AREAS	X			
j. NOISE CONTROL		X		
k. VIBRATION CONTROL	X			
l. FACILITIES FOR SANITIZING MATERIALS	X			
m. ENVIRONMENTAL MONITORING	X			
20. SPECIAL FACILITIES				
a. SURGERY	X			
b. BARRIER FACILITIES				X
c. IMAGING	X			
d. WHOLE BODY IRRADIATION				X
e. HAZARDOUS AGENT CONTAINMENT	X			
f. BEHAVIORAL STUDIES	X			
g. AQUATIC SPECIES HOUSING				X
21. SECURITY AND ACCESS CONTROL	X			

Appendix 10: IACUC/OB Periodic Report

SECTION V - REMARKS

SECTION I - ANIMAL CARE AND USE PROGRAM

Program Oversight-The Role of the IACUC 2.a(3a-e)- The IACUC does not have policies in place to address special considerations for IACUC review (b)(5)
(b)(5)

Program Oversight-The Role of the IACUC 2.a(2)- Protocols are not undergoing an appropriate safety/biohazard review during the protocol review process. (b)(5)
(b)(5)

Program Management-Personnel Management 1.b (1c-d)- There is no system in place to adequately track training requirements of the IACUC and the Research Team to determine if requirements are being met and timelines are being adhered to.

SECTION II - ENVIRONMENT, HOUSING, AND MANAGEMENT
Terrestrial Animals- Environment- Noise and Vibration 4.e- One of the (b)(6) rooms had a loud air ventilation tube - may need a baffle or noise suppressor of some type

SECTION IV - PHYSICAL PLANT
Functional Areas 18- Safety notices need to be updated with current POCs

Construction Guidelines- Floors 19.d- Many boxes on the floor hindering movement in (b)(6)

Construction Guidelines- Noise Control 19.j- One of the (b)(6) rooms had a loud air ventilation tube - may need a baffle or noise suppressor of some type

Room	Issue
(b)(6)	Bottle of expired saline on table
(b)(6)	Medical Maintenance Verification past due on environmental chamber; unknown whether calibration is done yearly or bi-yearly on environmental chambers
(b)(6)	2 table top scales were past calibration due date
(b)(6)	Fridge past due for Med Maintenance certification
	Carbon dioxide tank was labeled 11/2016 - verify that this is not expiration date
	Emergency shower testing is supposed to be done weekly, but last test was 11 AUG 2017
(b)(6)	Many boxes on the floor hindering movement in room
	Large sheet of metal draped over sink
(b)(6)	Kitchen air vent had a lot of dust, needs to be cleaned

DD FORM 2856, MAY 2012 Page 4 of 4 Pages

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, ***including all satellite facilities***. Include ***all animal holding rooms*** (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

Location/Building/Facility:	USARIEM (b)(6)	

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, *etc.*)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

HVAC system consists of a custom made air handling unit (AHU) located (b)(6) (b)(6) The AHU takes outside air and conditions the air. Animal housing rooms are controlled individually by a combination of steam-reheating coil and steam humidifier. This allows a temperature between 20-32°C (+/- 1°C) and relative humidity of 30-60% (+/- 5%) for each animal room. The valves in the reheat coils are designed to fail in the closed positions. The HVAC system is controlled by a digital computerized building management system (BMS). This allows for 24/7 remote monitoring and control of each room in the vivarium. The BMS is equipped with a database that allows trending and graphical representation of ambient temperature and relative humidity in each room. When a system failure occurs or room parameters go outside designated ranges and an alarm in the system goes off, the BMS is set up to notify the facilities supervisor through his cell phone (24/7). The facility supervisor notifies VSOB personnel (Chief, VSOB and technicians) of the issue.

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. *Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed* ***within the 12 months preceding completion of this Program Description.*** Air exchange rates may be important to maintain air quality in other areas; *however, measurements may be left at the discretion of the institution.* Information may be provided in another format, providing all requested data is included. **[*Note*: Please remove the examples provided in the Table below.]**

Room No.	**Specific Use**	**Temperature Set-Point** (define units)	**Electronic / Emergency Monitoring of Temperatures** (Y/N)	**Alert/Alarm Temperature Ranges** (if applicable; define units)	**Humidity Control** (Y/N)	**Relative Pressure**	**Air Exchange Rate** (per hour)	**Date Verified / Measured**
		(settings to be verified)					**(values to be measured)**	
(b)(6)	Surgery	70.5°F	N/A	N/A	Y	+	15	3/2018
	Animal Housing Room – Mouse Conventional	72°F	Y	73-74°F (alert) <70°F or > 74°F (critical alarm)	Y	++	16.2	3/2018
	Animal Housing Room – Rat	72°F	Y	73-74°F (alert) <70°F or > 74°F (critical alarm)	Y	-	17.6	3/2018
	Animal Housing Room – Rat	72°F	Y	73-74°F (alert) <70°F or > 74°F (critical alarm)	Y	+	17.6	3/2018

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
		(settings to be verified)					(values to be measured)	
(b)(6)	Animal Housing Room – Rat	72°F	N	73-74°F (alert) <70°F or > 74°F (critical alarm)	Y	-	14.4	3/2018
	Necropsy	70°F	N	NA	Y	+	N/A	3/2018
	Clean Cage Wash	70°F	N	NA	Y	++	4.45	3/2018
	Feed Storage	40-50°F	Y	>70°F	Y	+	0	3/2018
	Procedure Room	70°F	Y	<70 and >74°F	N	N/A	17.2	3/2018

[Create additional rows by pressing TAB in the bottom-right box.]

Copy and repeat the Description and Table for each location, including all satellite housing location.

Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies.

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Rat	145 in^2 (Tecniplast) 132 in^2 (Ancare)	See Chart	The Guide	Static Micro-isolator, Polycarbonate
Mouse	82in^2 (Tecniplast) 132 in^2 (Ancare)	See Chart	The Guide	Static Micro-isolator, Polycarbonate

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Tecniplast (Rat: 145in^2, Mice 82 in^2)

Animal	Weight (grams)	Animals per Cage (max)
Rat	<100	8
	Up to 200	6
	Up to 300	5
	Up to 400	3
	Up to 500	2
	>500	1
Mice	<10	13
	Up to 15	10
	Up to 25	6
	>25	5

Ancare (132 in^2)

Animal	Weight (grams)	Animals per Cage (max)
Rat	<100	7
	Up to 200	5
	Up to 300	4
	Up to 400	3
	Up to 500	2
	>500	1
Mice	<10	22
	Up to 15	16
	Up to 25	11
	>25	8

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Corridors:				
Floors	Mopping and sweeping	Once weekly or as needed	Didecyldemehylammonium chloride	
Walls	Hand Washing	As Needed	Didecyldemehylammonium chloride	
Ceilings	Swiffer Duster	As Needed	N/A	
Ducts/Pipes	Hand Washing	As Needed	Didecyldemehylammonium chloride	
Fixtures	Hand Washing	As Needed	At the end of study	
Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:				
Floors	Mopping and sweeping	Once weekly or as needed	Didecyldemehylammonium chloride	
Walls	Hand Washing	As Needed	Didecyldemehylammonium chloride	
Ceilings	Swiffer Duster	As Needed	N/A	
Ducts/Pipes	Hand Washing	As Needed	Didecyldemehylammonium chloride	
Fixtures	Hand Washing	As Needed	At the end of study	
Implements (note whether or not shared):				
Mops	Mechanical Cage Washer	At the end of the study or as needed	Sulphamic acid and alkoxylated ether, urea, sodiumcumenesulphonate	

Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Mop buckets	Mechanical Cage Washer	At the end of the study or as needed	Sulphamic acid and alkoxylated ether, urea, sodiumcumenesulphonate	
Other:				

Appendix 15: Facilities and Equipment for Sanitizing Materials

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
(b)(6)		Large Cage Washer	Emergency "off" safety cable to shut off cagewash, equipped with explosive-release latch requiring firm and rapid pressure against the door to open.	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; ATP swabs- based luminescence done monthly on items washed.
		Small Cage Washer Bottle Washer	Use caution when opening door due to steam pressure.	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; ATP swabs- based luminescence done monthly on items washed.
		Dump Station	PPE usage	ATP-based luminescence swabs performed quarterly on clean items
		None-hand washing	PPE usage	Visual assessment and ATP- based luminescence swabs performed quarterly on clean items
		Pressure Washing	PPE usage	Visual assessment and ATP- based luminescence swabs performed quarterly on clean items

Appendix 16: Lighting Summary

Location:	USARIEM (b)(6)

Room Type[a]	Light Intensity Range	Lighting Fixture Construction Features[b]	Photo-period (hrs)[c]	Photoperiod and Lighting Control	Override Mechanisms (if applicable)
Rodent Holding Rooms	130-300 lux	Surface mounted, water resistant	12:12	Automatic via building management system	Off switch to turn off automatic lights
Surgery	Not measured	Recessed, water resistant; arm-mounted, water resistant	NA	N/A	N/A
Necropsy	Not measured	Recessed, water resistant; arm-mounted, water resistant	NA	N/A	N/A
Cage-Washing Room	Not measured	Recessed, water proof	NA	N/A	N/A